Australian Government
Organ and Tissue Authority

Australian
PAIRED KIDNEY
EXCHANGE PROGRAMME AKX

Australian Paired Kidney Exchange (AKX) Programme

User Manual

Version 2 – August 2015

Index - Contents

1. National Reform Programme
2. AKX National Protocol
3. AKX Process
4. AKX Living Donor Evaluation Guidelines
5. AKX Tissue Typing Guidelines
6. AKX Ministerial Approval Process
7. AKX Agreement to participate for donors and recipient
8. National Guidelines for AKX Packaging and Transport
9. AKX NAT Protocol
10. AKX Donor CTA Protocol
11. AKX National Contact Details
12. AKX Programme – National Media Protocol

A World's Best Practice Approach to Organ and Tissue Donation for Transplantation

On 2 July 2008, the Australian Government announced a new national reform programme, **A World's Best Practice Approach to Organ and Tissue Donation for Transplantation.**

The aim of the Commonwealth-funded $151.1 million national reform programme is to establish Australia as a world leader in best practice organ and tissue donation and transplantation and to achieve a significant and lasting increase in the number of lifesaving and life-transforming transplants for all Australians that require this treatment.

The Australian Paired Kidney Exchange (AKX) Programme

The Australian Paired Kidney Exchange (AKX) Programme is a component of Measure 9 of the Commonwealth Government's world's best practice approach to organ and tissue donation in Australia. The measure aims to establish national protocols to guide initiatives including the practice of paired kidney exchange between living donors and recipients. It is expected that this donation will facilitate an increase in the donor numbers, thereby improving Australians' access to transplants, while ensuring that these practices operate in a safe, effective and ethical manner.

For some otherwise appropriate live donor/recipient pairs, ABO blood group incompatibility or human leucocyte antigen (HLA) sensitisation between donor and recipient are major barriers to live donor kidney transplantation. Between 6-8% of the waitlist patients have panel-reactive antibody (PRA) of >80% and are considered highly sensitised. Due to their high sensitivity, these patients are less likely to be allocated a deceased donor organ, resulting in extended waiting times.

AKX aims to maximise the number of live donor kidney transplants that can be performed in Australia. To achieve this purpose, AKX increases live donor kidney transplants by exchanging organs between biologically incompatible donor/recipient pairs. In this paired exchange, a recipient and their willing, but incompatible live donor agree to exchange kidneys with another incompatible pair so that both recipients receive compatible organs from strangers.

Participants in the AKX Programme include individuals willing to donate a kidney to their chosen recipient. Such donors must also be willing to donate their kidney to someone they do not know, while their intended recipient receives a kidney from an unknown donor who is also part of an incompatible donor/recipient pair. For some patients, paired kidney exchange may provide their only opportunity for transplantation.

A paired kidney exchange occurs when a live donor (Donor #1) is willing to donate to a spouse, friend or relative (Recipient #1), but cannot do so because they have an incompatible blood type or tissue type. AKX, through its database of registered pairs, helps to find another pair in the same situation (Donor and Recipient #2) who might be a match with Donor and Recipient #1. By exchanging donors, two compatible matches are created. The introduction of three-way exchanges is more complex but can increase the number of pairs transplanted by 50%. A simple two-way exchange is shown below:

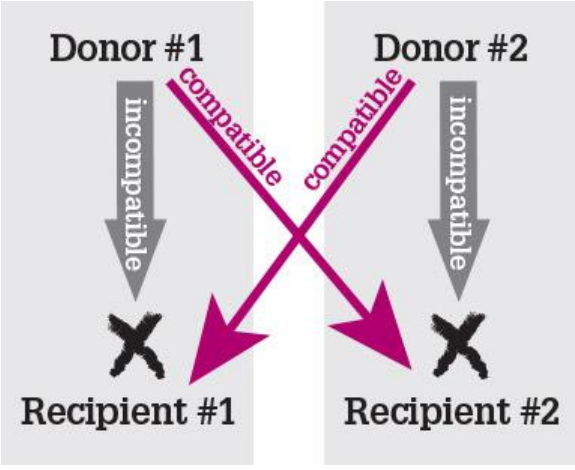


Figure 1: Paired kidney exchange

National Protocol for the Australian Paired Kidney Exchange Programme

Part 1: General Principles and structure of the AKX Programme

1. Introduction

The Australian Paired Kidney Exchange (AKX) Programme is a nationwide live kidney donor programme. The goal of AKX is to increase live kidney donor transplants by identifying matches for incompatible donor-recipient pairs. Consistency across all centres is essential for the success of the programme.

For the purpose of recruiting and assessing donor-recipient pairs, the following 22 transplant centres have been identified to participate in AKX.

For the purpose of donor retrieval surgery 13 transplant centres have been identified to perform a sufficiently large number of living donor surgeries per annum to satisfy the criteria recommended by the Transplantation Society of Australian and New Zealand (TSANZ) Donor Surgeons Donor Coordinators Advisory Committee.

State	Transplant Centre	Retrieval Transplant Centre
New South Wales	Westmead Hospital The Children's Hospital at Westmead Royal Prince Alfred Hospital Prince of Wales Hospital Sydney Children's Hospital Royal North Shore Hospital St Vincent's Hospital John Hunter Hospital	Westmead Hospital Royal Prince Alfred Hospital Prince of Wales Hospital Royal North Shore Hospital John Hunter Hospital
Queensland	Princess Alexandra Hospital Mater Children's Hospital	Princess Alexandra Hospital
South Australia	Royal Adelaide Hospital The Women's and Children's Hospital	Royal Adelaide Hospital
Victoria	Royal Melbourne Hospital Royal Children's Hospital Monash Medical Centre Monash Medical Centre (paediatric) Austin Hospital St. Vincent's Hospital Alfred Hospital	Royal Melbourne Hospital Monash Medical Centre Austin Hospital Alfred Hospital
Western Australia	Sir Charles Gairdner Hospital Fiona Stanley Hospital Princess Margaret Hospital	Sir Charles Gairdner Hospital Fiona Stanley Hospital

The purpose of this document is to inform **transplant centres performing donor nephrectomies, those performing the transplant in the recipient, renal specialists, tissue typing laboratories, the National Organ Matching Service (NOMS) and jurisdictional stakeholders** of the Protocol for the AKX Programme.

The Protocol consists of 2 specific parts:

Part 1: General Principles and Structure of the AKX Programme
Part 2: Process of the AKX Programme

2. AKX Programme – General Principles[1]

1. AKX will follow international and Australian best practice in living kidney donation and transplantation.

2. AKX will be governed by principles of good governance involving transparency, accountability and equity whereby the management and operation of AKX complies with ethical, financial, and legislative requirements, as well as relevant policy and frameworks.

3. AKX will support ethical practice, including upholding respect for donors, ensuring equity in allocation of organs, and maximising benefits of paired kidney exchange to recipients.

4. AKX will protect the interests and well-being of participants by:
   - ◊ placing paramount importance on the safety and interests of the donors and recipients;
   - ◊ using recruitment methods that are non-coercive, equitable and respectful of individual freedom of choice;
   - ◊ ensuring that participation of donors and recipients is based on voluntary and informed consent;
   - ◊ informing participants of their right to withdraw from the Programme at any time, for any or no reason, and any implications of doing so; and
   - ◊ undertaking any reasonable step to protect the confidentiality and privacy of donors and recipients.

5. AKX will require simultaneous anaesthetic induction time (AIT) for donor operations to ensure fair exchanges.
   - ◊ deviations from simultaneous AIT dictated by constraints due to availability of carriers for organ transport that would result in exceedingly long cold-ischaemia time may be negotiated on a case-by-case situation.
   - ◊ agreement to deviate from simultaneous AIT will require consent from all teams involved as well as from participating pairs who could be disadvantaged by non-simultaneous AIT.

6. For optimal operation, AKX will rely upon centralised national coordination, and cooperation between participating transplantation centres, tissue typing laboratories and the National Coordination Centre.

7. AKX seeks to increase overall numbers of living kidney transplants. In doing so however, AKX will also take into account the disadvantage in opportunities for successful transplantation generally experienced by O blood group and immunologically sensitised individuals.

The AKX General Principles were developed by the National Paired Kidney Exchange Programme Advisory Group: An advisory group of the National Cognate Committee on Organ & Tissue Donation & Transplantation.

[1] AKX General Principles from the AKX Guidelines, Australian Paired Kidney Exchange Programme Advisory Group: An advisory group of the National Cognate Committee on Organ and Tissue Donation and Transplantation, 2008, page 7.

3. Structure and Coordination of the AKX Programme

The AKX Programme includes the following operational features: National Coordination Centre, National Organ Matching Service (NOMS), Local Tissue Typing Laboratories and Transplant Centres.[2]

3.1 National Coordination Centre

The AKX Programme includes a National Coordination Centre whose responsibility is to coordinate, liaise and closely collaborate with transplant centres and tissue typing laboratories. It will maintain standard (harmonised) protocols and processes for:

- enrolling donors and recipients;
- ensuring consent to participate in the AKX Programme has been obtained from donors and recipients;
- obtaining approval from Ministers of Health, in accordance with state legislative requirements;
- ensuring donor/recipient pairs are fully evaluated and medical/surgical assessment is complete, in line with agreed national criteria;
- safeguarding the privacy of all participants and protecting personal medical information, including genetic information;
- ensuring close and consistent collaboration with local transplant centres and tissue typing laboratories;
- coordinating transport plans and organising donor organ transport and
- ensuring uniform standards for organ packaging and transportation. Transportation will be coordinated through the National Coordination Centre and be funded through the AKX Programme.

The National Coordination Centre comprises the following staff, funded through the AKX Programme:

Clinical Director - responsible for the overall management of the Programme including:

- supervising the AKX Programme Coordinator
- reviewing the policies and protocols of AKX
- liaising with State Transplant Centres
- liaising with the Coordinating Tissue typing Officer/HLA laboratory Director and NOMS
- liaising with RTAC surgical representatives to consult on potential donors with equivocal renal anatomy
- liaising with RTAC for advice and endorsement of relevant changes in policies and procedures
- liaising with and reporting to the RTAC AKX Clinical Oversight Subcommittee at quarterly intervals and
- reporting to the AKX Oversight Committee regarding activity, process changes and requirements for new policies and procedures

AKX Programme Coordinator - responsible for:

- liaising with local transplant centres to coordinate the registration of donor and recipient pairs
- liaising with State Health Departments regarding Ministerial Approval
- liaising with the Coordinating Tissue Typing Officer
- ensuring immunological crossmatches are performed and reported prior to surgical clearance
- facilitating surgical review of identified matches and identification of an appropriate date for exchange surgery
- coordinating transport plans and surgery details of scheduled exchange surgeries with local transplant centres
- supervising and coordinating organ transport during exchange surgeries
- reviewing policies and protocols of AKX

[2] The Structure and Coordination of the AKX Programme is part of the AKX Guidelines, developed by the AKX Australian Paired Kidney Exchange Programme Advisory Group: An advisory group of the National Cognate Committee on Organ and Tissue Donation and Transplantation, 2008, page 8.

Coordinating Tissue Typing Officer - responsible for:

- ◊ liaising with state tissue typing laboratories to coordinate and monitor consistent blood sera and tissue typing
- ◊ ensuring the final tissue matching quality of the transplant pairs
- ◊ determining acceptable/unacceptable tissue matching
- ◊ coordinating final donor/recipient cross-matching between matched pairs
- ◊ reviewing Tissue Typing/NOMS policies and procedures for AKX
- ◊ reporting to the Authority and National Coordination Centre on the TTL activity and issues

Coordinating HLA Laboratory Director
This position is not an AKX-funded position but is sourced from within the contracted laboratory infrastructure. This position will provide high level tissue typing expertise to AKX for case management and policy/programme development.
The Coordinating Tissue Typing Officer will undertake their assigned tasks in consultation with the HLA Laboratory Director.

3.2 National Organ Matching Service

The National Organ Matching Service (NOMS) has developed validated software with agreed, clear and transparent algorithms to match donor and recipient pairs. This is known as the NOMS Paired Kidney Exchange (PKE) Module. All AKX immunological information is maintained in the NOMS database, with access only available to authorised NOMS users.

The NOMS PKE programme is used by the CTTO for performing the 3 monthly match runs (unless no new pairs have been added to the registry) that will identify potential matches between AKX donor/recipient pairs.

State based tissue typing laboratories will enter tissue typing data into the NOMS database for all pairs registered in their State, and in accordance with the agreed Standard Operating Procedures. (See Tissue Typing Laboratory Guidelines for the AKX Programme.)

3.3 AKX Registry on Medical Message Exchange (MMEx)

Medical Message Exchange (MMEx) is an eHealth platform designed as a simple and secure application that allows users to enter patient information, view relevant data and documents, and correspond with other MMEx users.

The role of the AKX Registry on MMEx is to provide an electronic platform for clinicians to register donor/recipient pairs, access AKX forms and documents, and enable communication between transplant centres and the National Coordination Centre.

The National Coordination Centre is the administrator of the AKX Registry, and user access is limited to designated nephrologists and renal transplant coordinators at participating transplant centres. Transplant centres will only be able to enter and view patient details from their own centre. The local Tissue Typing Laboratories have “read-only” access to view registrants for their State for the purpose of facilitating tissue typing requirements.

The NCC as administrator is able to view all donor/recipient pairs on the registry, match potential pairs, and generate de-identified data from these matches that is forwarded to the relevant transplant centre clinicians.

For further information on the functionality of MMEx, please refer to the Australian Paired Kidney Exchange (AKX) Programme Registry User Manual on the MMEx portal.

4. Consent requirements and processes

AKX has clear and detailed protocols and processes in place regarding informed consent and registration on the AKX Registry. These protocols were developed by the AKX Advisory Group[3] and stipulate that each participating AKX transplant centre or Renal Service will:

- ◊ provide potential participants with required information on the nature, implications, foreseeable risks and benefits of their participation, so that they can realistically assess the implications of their participation prior to consent;
- ◊ obtain written informed consent, known as the Agreement to Participate, from each participating donor and recipient pair in accordance with agreed protocols; and
- ◊ inform donors and recipients that they may exercise their right to withdraw for any or no reason, at any time up to the commencement of surgery.

The information provided will be presented in a non-coercive way that supports individual decision-making and does not create an improper inducement to participate in AKX.

Important elements in optimising voluntary informed consent in this setting include:

(i) Interview of the donor conducted apart from the recipient
(ii) Donor assessment processes independent from the recipient team
(iii) Separate and distinct agreement to enter AKX (not an assumption when found incompatible for directed donation)
(iv) The Donor Agreement to Participate also includes mandatory completion of the Donor Declaration and the requirement for Nucleic Acid Testing (NAT) prior to surgery
(v) Detailed explanation of all the existing conditions of participation in the AKX Programme, as outlined in the Agreement to Participate documents and the AKX Protocol
(vi) Mandatory pre-donation counselling with an option of post-donation counselling as required.

The informed consent process will include reference to the human biological materials and data to be collected and the health and other records to be accessed, their intended uses, storage and duration of storage, transfer and disposal procedures. In this regard, each transplant centre will follow its own specific ethical guidelines.

The informed consent process must ensure that participants understand the requirement for, and agree to, disclosure of necessary identifying information to enable application for Ministerial approval.

Where an AKX policy, protocol or procedure is significantly modified, the National Coordination Centre will, where feasible, ensure that a new consent is obtained from participants on the register who are not yet scheduled for pairing.

Where AKX intends to actively seek data, information or other linkages about its participants from third party sources, it will disclose this to participants, and obtain the informed consent of the participant.

AKX will ensure that policy addresses appropriate contingency plans in the rare event of an 'orphaned recipient' (see section 5) where transplantation could not proceed as planned. This policy will include requisite consent from donors and/or recipients. The conditions whereby an "orphaned kidney" and an "orphaned recipient" result, and the planned outcomes for these contingencies, must be clearly explained to AKX participants to ensure consent is fully informed.

[3] National Paired Kidney Exchange Programme Advisory Group: An advisory group of the National Cognate Committee on Organ & Tissue Donation & Transplantation, AKX Guidelines, page 13

5. Protocol for orphaned kidneys and recipients

Definitions

Orphaned kidney: Refers to a kidney removed from an AKX donor that cannot be transplanted into the matched recipient.

Orphaned recipient: Refers to an AKX recipient whose co-registered donor has donated, but who has been unable to receive a kidney from the matched donor

The protocol for orphaned kidneys and orphaned recipients has been developed by the National Paired Kidney Exchange Programme Advisory Group[3] and revised as required by AKX Oversight Committee[4].
In the rare event where an exchange cannot proceed due to unforeseen clinical or logistical circumstances, the following is recommended:

5.1 Orphaned kidney

A recipient may acutely deteriorate during induction or during their operation such that the procedure needs to be abandoned. If the donor has already had their kidney removed, this results in an 'orphaned kidney'. Donors are asked to consider in advance whether, in this rare circumstance, they would be willing for their kidney to be allocated to someone suitable on the transplant waiting list. It is precisely for this unlikely, but possible, contingency that donor blood samples are taken at anaesthetic induction and transported with the kidney.

Once the originally intended recipient has recovered and is suitable for transplantation, his/her incompatible co-registered donor will already have donated a kidney in the AKX Programme. This recipient will receive priority for a suitable kidney from the deceased donor organ pool (refer to 'orphan recipient' below).

5.1.1. Process for determination and allocation of an orphaned kidney

Recipient Centre
Must immediately notify the AKX NCC if the recipient has become acutely ill and is unable to undergo or continue with transplant surgery.

Steps for allocation of an orphan kidney

- ◊ The NCC will determine current location of orphaned kidney:
  - If kidney is in transit, the state of destination will be the beneficiary of the incoming kidney
  - If kidney is still in the state of origin, it will be allocated to a transplant waiting list recipient within this state
- ◊ The NCC will alert the CTTO to perform urgent NOMS search / virtual crossmatch to identify a suitable recipient
- ◊ The CTTO will notify the NCC about the identified potential match (State of origin or State of destination) and the transplanting centre under which the identified recipient is listed
- ◊ The NCC will contact recipient's transplant centre to alert of the probable allocation. The de-identified MMEx live donor report will be made available to the recipient's team
- ◊ The CTTO will alert relevant Tissue Typing Laboratory to prepare for an urgent cross-match test
- ◊ The Tissue Typing laboratory performing the crossmatch will send a report to the recipient's centre, with copy to the NCC and CTTO and ensure the waiting list recipient centre has been duly informed
- ◊ The NCC will report the critical incident to the OTA/AKX Oversight Committee and monitor outcomes
- ◊ The NCC will facilitate communication of the resultant issues and outcomes between donor and recipient centres as required

[3] National Paired Kidney Exchange Programme Advisory Group: An advisory group of the National Cognate Committee on Organ & Tissue Donation & Transplantation, Page 18-19.
[4] AKX Oversight Committee: OTA , AKX Programme Director & RTAC Chair

5.2 Orphaned recipient

There may be multiple reasons for this eventuality, some of which are:

- ◊ donor nephrectomy could not be completed due to donor becoming acutely ill during surgery
- ◊ kidney was lost in transit or the wrong kidney was delivered
- ◊ kidney received by transplanting hospital was damaged during transport or packaging is found to be inappropriate
- ◊ kidney received by transplanting hospital was unable to be transplanted due to surgical issues
- ◊ recipient is acutely unwell and cannot undergo transplant surgery (see 'orphan kidney')

The outcome is that the intended recipient cannot receive a kidney, and is therefore an 'orphaned recipient'. The recipient's co-registered donor has already donated his/her kidney and thus the recipient no longer has recourse to an exchange. In this situation, the 'orphaned recipient' will receive NOMS priority listing (Level 3-4 interstate exchange) for a suitable kidney from the national deceased donor organ pool.

Pre-emptive recipients are not listed in NOMS, as activation on the deceased donor waitlist starts with the first day on dialysis. In these cases, exception will be made after notification and approval by RTAC that the pre-emptive recipient can be listed for priority allocation on the NOMS deceased donor waiting list.

IMPORTANT: If a kidney is transplanted and kidney reperfusion has been established, the recipient will not be considered an orphan recipient, even if the kidney never functioned.

Process for determination of an orphaned recipient and subsequent allocation of a kidney:

Donor Centre

Must immediately notify the AKX NCC if:

- ◊ the donor becomes acutely ill during surgery
- ◊ there are unforeseen surgical issues which result in an aborted nephrectomy
- ◊ the removed kidney is visibly damaged at the time of removal or during packaging

Recipient Centre

Must immediately notify the AKX NCC if:

- ◊ the kidney has not reached the hospital by the expected delivery time
- ◊ the kidney delivered is not for the intended recipient
- ◊ the transplant surgeon determines that the kidney received is not suitable for transplant eg. kidney is damaged
- ◊ the recipient becomes acutely ill during surgery, and the kidney can't be transplanted in the intended recipient on that occasion.

The National Coordination Centre

The NCC will:

- ◊ immediately advise the recipient centre when an aborted donor nephrectomy has been reported and a kidney will not be forthcoming
- ◊ work with the courier company to locate a delayed/lost kidney
- ◊ if kidney cannot be found, or is deemed unsuitable, alert the CTTO/ NOMS to instigate priority listing for the orphaned recipient
- ◊ report the critical incident to the OTA/AKX Oversight Committee and monitor outcomes
- ◊ facilitate communication of the resultant issues and outcomes between donor and recipient centres as required. In the first instance, transplant surgeons may wish to discuss orphan recipient status with the retrieval surgeon, and then escalate to the AKX Programme Director and the OTA National Medical Director as necessary.

The Donor and Recipient Agreement to Participate form expressly addresses "orphan kidney" and "orphan recipient" eventualities, which must be discussed during the consent process, and clearly understood by the potential donor and recipient pairs.

6. Protocol for altruistic donors

Use of non-directed ('altruistic') donor kidneys[4]
The use of non-directed donor kidneys in AKX should be available as an option to referring clinicians in States where this donation practice is permitted. This is a decision to be made by referring clinicians and AKX. It may be appropriate that an attempt is initially made to match a non-directed donor kidney to a highly sensitised patient on the deceased donor waiting list. If no match is found, that kidney may then be allocated to AKX.

7. AKX Documents and Confidentiality

The AKX Programme requires the maintenance of confidentiality of all donor/recipient details, and the preservation of anonymity between exchange pairs.
Therefore, filing of certain AKX documents must be carefully considered in terms of access of information. It is highly recommended that each centre has a designated AKX confidential filing system, accessible to designated authorised personnel only.

Specific guidelines as follows:

- ◊ All standard information for donor/recipient pairs that does not identify an exchange donor and/or recipient is filed as per current hospital protocol, i.e. in individual medical record.

  These documents are:

  1. *AKX Agreement to Participate for Donors and Recipients*
  2. *Donor Declaration Form*
  3. *AKX Ministerial Approval Form*
  4. *AKX Donor/Recipient Registration Forms (if printed from MMEx)*
  5. *AKX Tissue Typing Registration Form*

- ◊ Specific AKX documents which identify participating pairs in an exchange, and details on donor/recipient information from other centres (e.g. when an exchange has occurred) must not be filed in the patients' medical record.

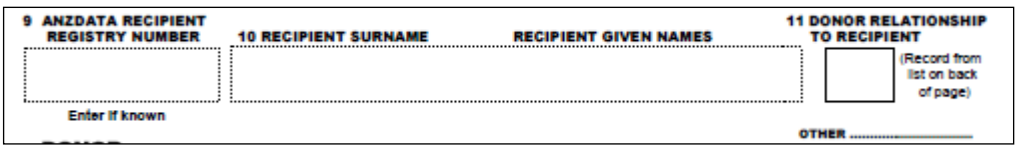
  These documents are:

  1. *AKX Surgical Checklist Form*
  2. *AKX Living Kidney Donation Report*
  3. *Exchange Donor CTA report and images*
  4. *AKX Match View information*

8. ANZDATA and post transplant reporting

Standard reporting using the Australia and New Zealand Dialysis and Transplant Registry (ANZDATA) Living Kidney Donor Registry forms and ANZ Dialysis & Transplant Survey sheet remains the same, with the following conditions:

(i) Living Kidney Donor Registry – Pre-Transplant Data form
Complete all data as required on form, leaving recipient details #9 and #10 blank.

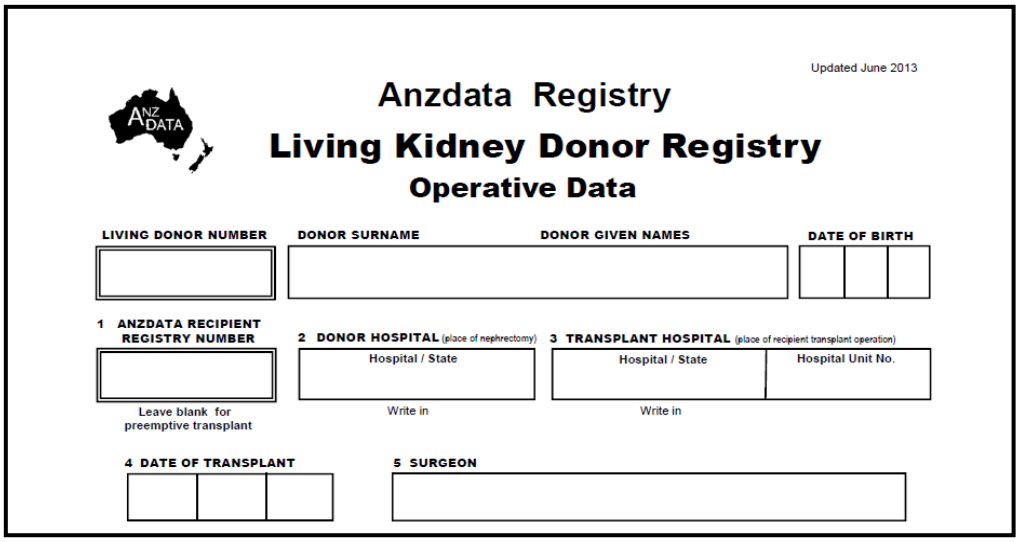

9 ANZDATA RECIPIENT REGISTRY NUMBER
10 RECIPIENT SURNAME
RECIPIENT GIVEN NAMES
11 DONOR RELATIONSHIP TO RECIPIENT
(Record from list on back of page)
Enter if known
OTHER .....

Enter # 15 (Paired Kidney Exchange) in **Donor Relationship to Recipient** box, and specify as **PKE**.
The AKX National Coordination Centre will provide recipient details to ANZDATA, upon advisement of receipt of ANZDATA form.

(ii) Living Kidney Donor Registry – Operative Data form

Use the AKX Living Kidney Donation Report form and your centre's operation report to complete the information required. The **ANZDATA Recipient Registry Number** (Box 1) will not be available hence leave blank.

◊ Box 2 denotes the Donor Hospital – the place of nephrectomy
◊ Box 3 denotes the Transplant Hospital – the place of recipient transplant surgery. This is in the majority of cases at a centre other than the Donor Hospital and in another State


Updated June 2013

Anzdata Registry

Living Kidney Donor Registry

Operative Data

LIVING DONOR NUMBER | DONOR SURNAME | DONOR GIVEN NAMES | DATE OF BIRTH

1 ANZDATA RECIPIENT REGISTRY NUMBER (Leave blank for preemptive transplant)

2 DONOR HOSPITAL (place of nephrectomy) Hospital / State (Write in)

3 TRANSPLANT HOSPITAL (place of recipient transplant operation) Hospital / State (Write in) | Hospital Unit No.

4 DATE OF TRANSPLANT

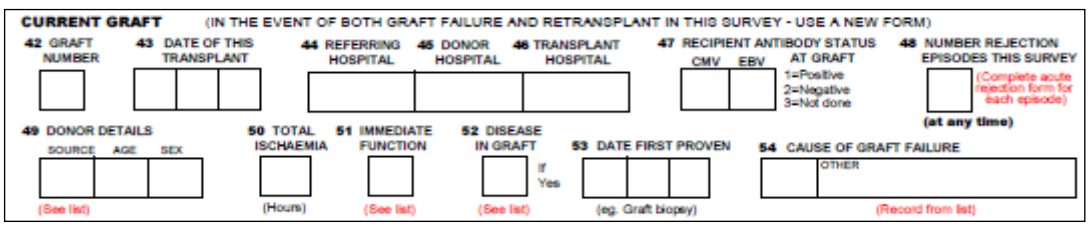
5 SURGEON

(iii) Real Time Web Data Entry

Notifying a change in treatment course ie. transplantation, requires the same donor data as specified above. Please enter **Donor Source** as #15, **PKE**.

(iv) ANZ Dialysis & Transplant Survey sheet (for recipients)

Current Graft section: Question 49, **Source of Donor Kidney** enter as #15 from list (PKE). Other operative data required may be obtained as previously detailed in Point 2(ii).


CURRENT GRAFT (IN THE EVENT OF BOTH GRAFT FAILURE AND RETRANSPLANT IN THIS SURVEY - USE A NEW FORM)

42 GRAFT NUMBER | 43 DATE OF THIS TRANSPLANT | 44 REFERRING HOSPITAL | 45 DONOR HOSPITAL | 46 TRANSPLANT HOSPITAL | 47 RECIPIENT ANTIBODY STATUS AT GRAFT CMV EBV (1=Positive 2=Negative 3=Not done) | 48 NUMBER REJECTION EPISODES THIS SURVEY (Complete acute rejection form for each episode) (at any time)

49 DONOR DETAILS SOURCE AGE SEX (See list) | 50 TOTAL ISCHAEMIA (Hours) | 51 IMMEDIATE FUNCTION (See list) | 52 DISEASE IN GRAFT (See list) | If Yes | 53 DATE FIRST PROVEN (eg. Graft biopsy) | 54 CAUSE OF GRAFT FAILURE OTHER (Record from list)

These guidelines have been developed in collaboration with ANZDATA.

Part 2: Process for the AKX Programme

Pre-enrolment process, consent and Ministerial Approval

1 Initial discussion with incompatible donor/recipient pair

Who	Local Renal Specialist
Where	Local Renal Unit
What	Provide the recipient and their donor information on AKX including the AKX Information Brochure ➢ If donor/recipient wish to consider AKX go to 2.

2 Provide full information about AKX and other options of incompatible living kidney donation

Who	Transplant team nephrologist
Where	Local transplant centre
What	Provide the donor and recipient with full information about all the living donor options between an incompatible donor and recipient available to them and conditions of participation in AKX ➢ If donor/recipient agree to AKX go to 3.

3 Agreement to Participate in AKX & Ministerial Approval

The process for seeking donor and recipient agreement to participate and ministerial approval differs in each jurisdiction based on legal requirements. (See Ministerial Approval process for full details.)

The Agreement to Participate and Ministerial Approval by state is outlined as such:

All donors and recipients must sign an Agreement to Participate in the AKX Programme. (Donors are also required to complete a Donor Declaration form in the presence of the interviewer (physician or nurse). The Donor Declaration is not submitted with Ministerial Approval or uploaded onto MMEx, but a copy is required by the NCC.

If donor/recipient is a resident of ACT, NSW, TAS or WA, Agreement to Participate must be obtained prior to seeking Ministerial Approval. **Go to 3.1 then 3.2**.
ACT participants require Ministerial Approval from ACT and NSW MoH.
TAS participants only require Ministerial Approval if Agreements to Participate are signed in Tasmania.

If donor/recipient is a resident of SA or NT, Ministerial Approval must be gained prior to obtaining Agreements to Participate. **Go to 3.2 then 3.1.**
NT participants require Ministerial Approval from NT and SA MoH, even if the Agreements to Participate have been signed in SA.

If donor/recipient is a resident of QLD or VIC, Ministerial Approval is not required. **Go to 3.1.** However, if a donor or recipient co-registered with a QLD/VIC participant resides in NSW, WA, or SA and will have surgery in the home State, Ministerial Approval applicable to that State will be required.

3.1 Agreement to Participate

Who	Transplant team nephrologist
Where	Local transplant centre
What	Obtain signed Agreement to Participate Forms and Donor Declaration for the donor and recipient pair to participate in the AKX Program. Submit the Signed Agreement to Participate Form and Donor Declaration to the National Coordination Centre via MMEx upload, fax, or email.

3.2 Ministerial Approval to participate (not for QLD/VIC)

Who	Transplant team nephrologist
Where	Local transplant centre
What	Complete Section 1 of the Ministerial Approval Form Submit the Ministerial Approval Form to the AKX Programme Coordinator via MMEX upload, fax, or email.
Timing	The Ministerial Approval Process should take between 1-2 weeks.

Please note the following for the Ministerial Approval Process to be expedited:

- ◊ In SA/NT, a scanned copy of the Ministerial Approval document is acceptable for submission
- ◊ In NSW/ACT/TAS/WA scanned copies of Agreements to Participate and Ministerial Approval documents are acceptable for submission
- ◊ Scanned copies must be clearly legible or they may not be accepted. It is therefore recommended that a dark pen and block letters (other than signatures) are used when completing documents

Enrolment and medical evaluation

4 Medical Evaluation

Prior to activating a donor/recipient pair in the AKX registry both the donor and the recipient must already be determined to be medically suitable for the transplantation procedure. Pre-emptive recipients require medical suitability clearance by the local transplant centre and the submission of HLA serum samples to Tissue Typing laboratories as advised by the local TT officer.

Who	Transplant team nephrologist
Where	Local transplant centre
What	Determine donor (and the recipient) medical suitability for the transplantation procedure according to the *Guidelines for evaluation of living donors for Paired Kidney Donation*

Recommended guidelines for donor CT Angiogram protocol have been developed by AKX transplant surgeons and are provided at Attachment 4a.

5 Enter donor/recipient pairs into the AKX Registry

Registration of donor/recipient pairs may commence at any time during the medical assessment process, but the evaluation must be completed and the donor/recipient pair deemed medically and surgically suitable for transplantation, prior to activation on the AKX registry. A CD-ROM of the donor's CT angiogram, and the CT report, must be sent to the National Coordination Centre as soon as available (this is in addition to uploading images onto MMEx).

The CD-ROM of donor CTA and CTA report must not be de-identified.
Where an anatomical anomaly has been identified on the CT report eg. liver or kidney cyst, or an unidentified lesion, and further imaging has been recommended, please provide the relevant report in addition to the CT report.

Who	Transplant team nephrologist/renal transplant coordinator
Where	Local transplant centre
What	Enter data on donors and recipients into the AKX Registry via the web-based MMEx portal ➢ Forward a CD-ROM of the donor's CT angiogram, plus CT report, to the NCC ➢ Send AKX Tissue Typing Registration Form to state tissue typing laboratory

The Tissue Typing Laboratories usually won't accept new referrals 4 weeks prior to a match run (lock-down), at which time no further tissue typing will generally be undertaken. It is therefore important to submit the tissue typing registration form as soon as the donor-recipient pair have been deemed suitable for the program, and noting in Section 4 of the form for which match run the pair is likely to be ready (example below).

SECTION 4: This Form completed by			
Full Name: (please print)		**Position:**	
Signature:		**Date:**	
Hard copies of Blood group and Virology results attached (donor & recipient)			☐ **Yes**
Please indicate for which quarterly AKX Run this pair (or altruistic donor) will be ready			☐ **1st** ✓**2nd** ☐ **3rd** ☐ **4th**

6 Immunology data entered into NOMS

Paired kidney exchange specific tissue typing requirements are mandatory to enrol donor/recipient pairs in the AKX Programme.

For entry onto the PKD register:

Donors must have an authorised HLA typing at **4-digit level** recorded into the NOMS for each of the following mandatory HLA loci:

HLA-A*, HLA-B*, HLA-Cw*, HLA-DRB1*, HLA-DQB1*, HLA-DQA1*, HLA-DPB1* and HLA-DRB3/4/5*.

Sensitised recipients must have an authorised Class I and Class II HLA antibodies by solid phase single antigen bead assays (Luminex) at **4-digit level** recorded into the NOMS. DSA with MFI>2000 (One Lambda) or >1500 (Tepnel) excludes from matching.

AKX Tissue Typing requests should be submitted to the state tissue typing laboratory with these specifications, and noting that the request is specific to the AKX programme (sample request forms are included in the Tissue Typing Guidelines)

Who	Local tissue typing officer
Where	State tissue typing laboratory
What	Enter donor/recipient immunology data (containing donor HLA type and recipient HLA type, sensitisation history and acceptable mismatches) into NOMS.

7 Confirmation of donor and recipient pair information

In addition to the standard AKX Donor criteria, all donors must have an identified Blood Group result uploaded onto MMEx. Blood Group A donors are also required to be subtyped as this is important information for any potential Blood Group incompatible transplant.

Who	AKX Programme Coordinator
Where	National Coordination Centre
What	The National Coordination Centre will confirm that the referring transplant centre has fully evaluated the submitted donor/recipient pairs: ▪ Donor medical work-up is complete; ▪ The donor/recipient information is complete, including: ▪ CD-ROM and report of the donor CT angiogram have been received; and ▪ Donor/recipient pair immunology information has been completed. 2 weeks prior to TT lockdown, a match run reminder will be sent to centres. At this time, the NCC will also request preliminary identification of pairs for possible inclusion in the match run. This information is provided to state laboratories to assist with prioritisation of workload. ➢ If medical and immunology evaluation are complete, **go to 8.**

Matching of pairs

8 Verification of active pairs

Who	AKX Programme Coordinator
Where	National Coordination Centre
What	One week before the intended match run: AKX Programme Coordinator to verify with Local Transplant Centres ▪ that all active registered donor-recipient pairs are for inclusion in match run ▪ Pre-emptive recipients have up-to-date HLA antibody testing and are suitable for transplantation ▪ Acceptance of ABOi and Hepatitis B core positive donors as registered in MMEx is confirmed in accordance with anti-blood group titres and recipient informed consent ▪ Blood group A donors have been subtyped and subtype has been entered into MMEx ▪ Donor blood group result (identified) has been uploaded onto MMEx

9 Provide list of active pairs to National Coordinating TTO

Who	AKX Programme Coordinator/ CTTO
Where	National Coordination Centre
What	AKX Programme Coordinator to: ▪ send Coordinating Tissue Typing Officer a list of current and potential active pairs one week before the run to ensure all immunological data is available, including sera for final cross match. The CTTO ensures NOMS data entry at local tissue typing laboratories has been completed ▪ confirms all active pairs one business day before the match run

10 NOMS Match Run

Who	National Coordinating Tissue Typing Officer
Where	National Coordination Centre
What	The CTTO will perform a NOMS match run every 3-months ▪ A report of the match run of matched donor/recipient pairs is sent to the National Coordination Centre ▪ Recipients who have not been matched to a suitable donor-recipient pair remain active on the NOMS list ▪ Recipients who have been matched to a suitable donor will be suspended from NOMS ▪ They will be reactivated in NOMS if the chain breaks down (positive crossmatch or other reasons) or removed from NOMS when the transplant has occurred.

11 Review of matched pairs

Who	AKX Clinical Director/ Programme Coordinator/ Coordinating Tissue Typing Officer/HLA Laboratory Director/local TT officers
Where	National Coordination Centre
What	▪ Review matched donor-recipient pairs. ▪ Transplant centres may be contacted with potential match information as a preliminary enquiry towards acceptance/rejection of proposed match ➢ If proposed matches are acceptable, **go to 12**.

12 Transplant teams notified of matched pairs required for immunological (CDC ± flow) cross matching

Who	AKX Programme Director/Coordinator	Coordinating Tissue Typing Officer
Where	National Coordination Centre / Local Transplant Centre	Coordinating tissue typing laboratory /State tissue typing laboratory
What	AKX Programme Director/Coordinator: ▪ Notify transplant teams, CTTO and State TTL's of identified potentially compatible pairs ▪ Enquires about the need for flow cross match requirements for recipients accepted with moderate level DSA ▪ Facilitates donor specific ABOi titre if required Local Transplant Centre: ▪ Book XM within 5 days of notification ▪ Recall matched donors to present to Transplant Centre for cross-matching ▪ Repeat serology for HIV/HBV/HCV and CMV/EBV	Coordinating Tissue Typing Officer: ▪ Coordinates cross matching with State tissue typing laboratory of identified potentially compatible pairs. State tissue typing laboratory: ▪ Prioritise AKX cross-matching. Cross matches are performed within 2 weeks

13 Review of cross matches

Who	AKX Clinical Director/ Programme Coordinator/Coordinating Tissue Typing Officer/Local State TTL
Where	National Coordination Centre
What	▪ Review CDC crossmatch and where appropriate, flow cytometric crossmatch results ▪ Approve acceptable exchanges following review of crossmatch results ▪ Provide appropriately de-identified cross match reports ▪ Notify state laboratories to re-activate recipients with positive cross-match on the NOMS list ➢ If proposed matches are confirmed, **go to 14.**

14 Transplant teams notified of matched pairs required for surgical cross matching

Once immunologic compatibility of a potential match is confirmed, the AKX Programme Director notifies the transplant teams of the proposed exchanges. A review of the viability of the proposed exchange will be required by donor and recipient liaison surgeons at the respective transplant centres by way of the Surgical Checklist and CD-ROM of Donor CTA. As the donor is identified in this instance, the signatories of this report guarantee to maintain anonymity of the donor, and will not disclose any donor information with other members of the transplant teams or recipient.
Coordination of surgery dates will be facilitated by the NCC, surgeons and renal transplant coordinators and should occur in consultation with nephrology/hematology departments if a Blood Group incompatible transplant is proposed.

Surgical review will take place in a 4 step process.

1. AKX Programme Coordinator completes donor/recipient information and forwards surgical checklist to donor surgeon. Donor CTA CD is sent to recipient centre at the same time
2. Donor Surgeon notes preference for kidney to be removed, completes preferences for perfusion solution/heparinisation, signs and returns form to NCC. AKX Programme Coordinator forwards the signed form to Recipient surgeon
3. Recipient Surgeon reviews donor kidney anatomy, and decides on acceptability of the proposed organ. The form is signed and returned to the NCC
4. The NCC distributes the signed surgical checklists to all involved centres as confirmation of the exchange

If an exchange has been determined as not viable by the recipient surgeon the checklist must be signed accordingly and returned immediately to the NCC. The NCC will take appropriate action in conjunction with the involved transplant centres.

Who	AKX Programme Director/ Coordinator	Recipient and Donor Liaison Surgeons
Where	National Coordination Centre / Local Transplant Centre	Local Transplant Centres
What	AKX Programme Coordinator: ▪ Sends CD-ROM/report of donor imaging to recipient liaison surgeon ▪ Sends Surgical checklists to donor and recipient liaison surgeons ▪ Action Surgical Cross-Match result as required.	Recipient & Donor Liaison Surgeons ▪ Complete and send Surgical Checklist to NCC. ▪ Advise NCC immediately if exchange not viable
	➢ If proposed matches are acceptable, **go to 15.**	

15 Transplant teams notified of authorised pairs for exchange

Upon notification of a potential exchange, transplant centres will confirm the surgery date acceptable to all parties. This date may have been previously negotiated between liaison surgeons at the time of surgical crossmatch.
In transplant centres where donor nephrectomy is performed by a urologist not usually involved in deceased donor transplants, it is understood that experience with packaging of the donor kidney will be limited. The consensus amongst donor and recipient surgeons is that, in these instances, a transplant recipient surgeon will be present in theatre to assist with this process.

Who	AKX Programme Director/ Coordinator
Where	National Coordination Centre
What	Notify transplant teams of the donor/recipient pairs selected for the exchange. ▪ Send de-identified donor information to recipient centre via MMEx (MMEx email is auto-generated to relevant transplant centre users when a MATCH – 'For Surgery' is confirmed on MMEx by the NCC)

16 Logistics for Exchange

Who	AKX Programme Coordinator
Where	National Coordination Centre
What	▪ Confirm date of surgery acceptable to Local Transplant Centres and donor/recipient pairs ▪ Inform the relevant State TT Officers of date of transplants ▪ Identify responsible person at each site that will oversee coordination of surgical timelines; and ▪ Confirm the requirement or otherwise for a transplant surgeon to be present in theatre to assist with packaging of donor kidney ▪ Send a preliminary transport itinerary to transplant teams to assist with operative scheduling

Before Surgery

17 Transport and Packaging resources available

The NCC will ensure that AKX transport packs consisting of container, trolley and packaging materials (AKX Transport Pack) are distributed to all transplant centres.

These packs are to be stored in a specially designated safe and secure area in the renal transplant department. These supplies will be replenished as necessary by the NCC upon request from the transplant centre.

Who	AKX Programme Coordinator and Local Transplant Team
Where	National Coordination Centre and Local Transplant Centre
What	▪ AKX Programme Coordinator to send AKX Transport Pack ▪ The Local Transplant Centre to ensure AKX transport pack is available prior to a potential exchange and check that surgical schedules are in place

18 Recipient Luminex Single Antigen Bead (SAB) testing

There may be a delay of several weeks between initial cross-match and surgery, increasing the risk of an adverse immunological outcome. Should transplants be delayed for any reason, **serum from within 4 weeks** of the transplant date will need to be retested by Luminex SAB, **if >2 months since crossmatch have elapsed**.

Who	AKX Programme Coordinator/ Local Transplant Centre/CTTO/Local TT lab
Where	National Coordination Centre
What	**If scheduled surgery is >2 months after crossmatch** At least 4 weeks prior to surgery, AKX Programme Coordinator will: ▪ Remind transplant centres of necessity for collection of HLA serum The CTTO/Local TT lab will: ▪ Review current SAB analysis ▪ Ascertain whether a further crossmatch is required

19 Consent for surgery and Donor Nucleic Acid Testing

Who	Local Transplant Centre/NCC
Where	Local Transplant Centre
What	▪ Obtain consent for surgery from donor and recipient as per hospital policy. ▪ Organise collection of donor NAT samples at required pre-surgery interval. This test must be requested as an URGENT test Send result to NCC as soon as available. ▪ The NCC will forward de-identified NAT result to recipient centre
	➢ If NAT results are negative, **go to 20** ➢ If NAT results are positive, **surgeries will be deferred**

20 Confirm Day of Exchange details

The AKX Programme Coordinator will confirm all logistical details with local transplant centres and ensure the AKX Organ Transport Itinerary has been distributed accordingly.

Who	AKX Programme Coordinator
Where	National Coordination Centre
What	One week prior to surgery AKX Programme Coordinator confirms: ▪ AKX Transport Packs have been received by each centre ▪ Anaesthetic start times and anticipated pick-up times for organs ▪ Donor Blood request forms for "PKE store cells" and Living Kidney Donation reports have been sent to centres ▪ Name of recipient transplant surgeon who will be present in theatre to assist with packaging (as applicable) ▪ Flight itineraries for organs (as applicable) ▪ Transport Plan, NXF numbers & Consignment Notes for Organ Transport have been received by centres ▪ Hospital pickup and delivery points and designated contacts at each hospital; and ▪ Back-up itinerary and emergency contact details

21 One day prior to surgery

Cross-checking of kidneys is an essential process to ensure the correct donor kidney is removed and transplanted into the matched recipient. To facilitate this, de-identified donor and recipient cross-match reports, donor NAT, ABO and CMV/EBV results are provided by the NCC. **Donor NAT, ABO, & CMV/EBV documents must accompany the donor kidney, in addition to the Living Kidney Donation report**. The 3 main identifiers used for all de-identified documents are:

- NOMS Identification Numbers
- Date of Birth
- Blood Group

Who	AKX Programme Coordinator
Where	National Coordination Centre
What	▪ Verify that all items in step 20 are confirmed; and ▪ Confirm with transplant centres that donor-recipient pairs are fit for surgery (not affected by acute illness, consent not withdrawn) ▪ Ensure de-identified copies of donor NAT, ABO & CMV/EBV documents are available at the donor centre

Surgery and post surgery

22 Day of surgery

Who	Transplant team
Where	Local Transplant Centre
What	▪ Confirm, in separate consultations, donor and recipients medical and emotional suitability to participate, advising them that they can withdraw at any time up until surgery ▪ Immediately notify the AKX Programme Coordinator and other Local Transplant Centre if donor and/or recipient withdraw ▪ Notify the AKX Programme Coordinator immediately of any last minute issue regarding consent, packaging, transport and surgery ▪ For Donor Surgery, ensure that section 1 and 2 of the Living Kidney Donation Report is completed appropriately and accompanies the kidney, along with the donor blood samples and deidentified NAT, ABO and CMV/EBV results ▪ For Recipient Surgery, ensure the kidney received is cross-checked and correct for the recipient prior to implantation

23 After transplantation

Who	Recipient Surgical Team / AKX Programme Coordinator
Where	Recipient Hospital / National Coordination Centre
What	Recipient Surgical Team: ▪ Complete section 3 of the Living Kidney Donation Report and forward to AKX Programme Coordinator within two working days of procedure ▪ AKX Programme Coordinator: Feedback any issues to transplant centres and Organ and Tissue Authority

24 Post Transplant Notifications

Who	AKX Programme Coordinator / Local Transplant team
Where	National Coordination Centre / Local transplant Centre
What	AKX Programme Coordinator: ▪ Completes NOMS renal transplant notification forms and sends to CTTO (for distribution to relevant states) and ANZDATA ▪ Requests recipient and donor post transplant data ▪ Requests feedback of any issues ▪ Completes and forwards ANZDATA forms received to ANZDATA Local Transplant Centre: ▪ Completes ANZDATA Living Donor Forms and forwards to AKX Coordinator for completion of recipient details ▪ Provides post transplant information as requested by NCC

25 Data collection

Who	AKX Programme Coordinator
Where	National Coordination Centre
What	AKX Programme Coordinator: ▪ Collect data on the outcome of the transplants and report annually to the Organ and Tissue Authority

Process of the Australian Paired Kidney Exchange (AKX) Programme

No	What	Relevant document
1	**Initial discussion with patient** Recipient is identified to have a medically suitable, but incompatible donor. Recipient and donor are given information on AKX (AKX Information Brochure). The local nephrologist is in the best position to judge whether or not the pair should consider the option.	FAQs
2	**Provide full information about the AKX Programme** Donor and recipient receive full information about the advantages and disadvantages of all of the living donor options available to them and agree to participate in AKX Programme after considerations of these options. An informed consent discussion list is available to ensure that consistent consent process and participants' information has been provided in each hospital.	Informed Consent Discussions Checklist
3	**Agreement to Participate and Ministerial Approval** All donors and recipients are required to sign Agreement to Participate forms to register in AKX Programme. 1) VIC & QLD **do not require** MoH approval - **go to 3.1** 2) NSW, ACT, TAS & WA **require** MoH approval **after** consenting to participate in AKX Programme - **go to 3.1 then 3.2** - ACT participants require signed approvals from ACT & NSW MoH 3) NT & SA participants **require** MoH approval **before** consenting to participate in the AKX Programme - **go to 3.2 then 3.1** - NT participants require signed approvals from NT & SA MoH	
3.1	**Agreement to Participate form signed** Signed agreements are obtained for the donor/recipient pair to participate in the AKX Programme and for information to be submitted to the National Coordination Centre (NCC). The donor is also required to sign the Donor Declaration form.	AKX Agreement to Participate Donor Declaration Form
3.2	**Ministerial approval** Documentation seeking Minister or delegate approval for AKX to be completed: ▪ The Transplant Centre to complete Section 1 of the Ministerial Approval Form and send the approval form to the AKX Programme Coordinator (fax or scanned copy) ▪ The AKX Programme Coordinator will forward Ministerial Approval request with signed agreements to participate (not applicable in SA) to State/Territory Health Department ▪ Once the Chief Health Officer (CHO) / Minister for Health (MfH) has signed and returned the form, the AKX Programme Coordinator sends the signed Approval form to the Local Transplant Centre and uploads the form onto MMEx	AKX Ministerial Approval Form

No	What	Relevant document
4	**Medical evaluation** Prior to activating a donor/recipient pair in the AKX registry both the donor and the recipient must be determined to be medically suitable for the transplantation procedure. Guidelines for assessing donor medical suitability including medical, surgical and psychological assessment are outlined in the AKX Living Donor Evaluation Guidelines. Guidelines for donor CT Angiogram are provided at in the Donor CTA Protocol. *Notes*: ▪ Recipients listed on the NOMS waitlist for deceased donor kidneys are considered to be medically suitable ▪ Pre-emptive recipients require medical suitability clearance by the Local Transplant Centre and the submission of HLA serum samples to Tissue Typing laboratories as advised by the local TT officer Donors require comprehensive medical suitability assessment by the Local Transplant Centre to certify their suitability for AKX.	AKX Living Donor Evaluation Guidelines AKX Donor CTA Protocol
5	**Enter donor/recipient pairs into the AKX Registry** Donor/recipient pairs are entered into AKX via the web-based MMEx registry by their Transplant Centre. AKX Tissue Typing Registration Form is sent to state tissue typing laboratory as soon as pair is clarified as suitable for AKX. Tissue Typing Labs have a lock-down period for Tissue Typing testing 4 weeks prior to a Match Run. **No Tissue Typing Registration Form by the time of lock-down = Exclusion from current match run.** A set of medical information and investigations of recipients and donors must be completed and entered into the registry to activate pairs in AKX. The specific recipient consent form in relation to the acceptance of Hepatitis B core antibody (anti-HBc) positive donors must be obtained and made available to the AKX Coordinator as required. A CD–ROM, including the CT report, of the identified donor CT angiogram must be forwarded to the NCC prior to activation on the registry.	Registered authorised users to access https://mmex.gsmhn.com.au/ AKX Tissue Typing Registration Form HBc positive donors – Recipient Consent form
6	**Immunology data entered into NOMS** Donor/recipient immunology data (containing donor HLA type and recipient HLA type, sensitisation history and acceptable mismatches) are entered into the NOMS by the state tissue typing laboratory. The Coordinating Tissue Typing Officer (CTTO) will liaise with the AKX Programme Coordinator and local labs to ensure timely laboratory testing.	AKX Tissue Typing Guidelines
7	**Confirmation of donor/recipient pair information** AKX Programme Coordinator confirms that the referring transplant centre has fully evaluated the submitted recipient/donor pairs: ▪ Donor medical work-up is complete ▪ The donor/recipient information is complete ▪ CD-ROM and report of donor CT angiogram has been received ▪ Donor/recipient pair immunology information has been completed	

No.	Action	Relevant document
8	**Verification of active pairs** One week before the intended match run the AKX Programme Coordinator verifies with Transplant Centres that: ▪ All active registered donor-recipient pairs are for inclusion in Match Run ▪ Pre-emptive recipients have up-to-date HLA antibody testing and are suitable for transplantation ▪ Acceptance of ABOi donors as registered in MMEx is confirmed ▪ Donors who are blood group A have been sub-typed ▪ Donor Blood Group results have been uploaded onto MMEx & not de-identified	
9	**Provide list of active pairs to CTTO** AKX Programme Coordinator: ▪ Sends CTTO a final list of current and potential active pairs one week before run to ensure all immunological data (HLA, acceptable MM etc) is available, including sera for final crossmatch ▪ Confirms all active pairs with CTTO one business day prior to match run	
10	**NOMS Match Runs** CTTO performs a NOMS match run every 3 months (unless no new pairs have been added to the programme).	
11	**Review matched pairs** The NCC reviews matched donor-recipient pairs with the CTTO and the State TT Officers. ▪ Recipients who have not been matched to a suitable donor-recipient pair remain active on the NOMS list ▪ Recipients on the NOMS transplant waiting list are temporarily suspended from NOMS if a match is identified ▪ CTTO provides the report of the match run and individual HLA antibody reviews of matched recipients to the AKX Programme Director and Coordinator	
11.1	**Equivocal matches** Depending on the identified combinations, the AKX Programme Director/Coordinator may contact transplant centre(s) with a preliminary inquiry about intention to accept/refuse a proposed match. Acceptable matches, go to 12.	
12	**Transplant teams notified of matched pairs required for immunological cross matching** AKX Programme Director notifies transplant teams and State TTL of accepted pairs. National Coordination Centre ▪ Facilitates donor-specific ABO-titre or flow-XM, if indicated. CTTO/State TTL ▪ Coordinate cross-matching of identified matched pairs at State laboratory ▪ Cross-matches are performed within 2 weeks Transplant Centre ▪ Recalls donors for cross-matching (XM booking to be made within 5 days of notification) and serology for blood borne viruses	

No.	Action	Relevant document
13	**Review of crossmatches** The NCC reviews cross-matches with the CTTO and State TTL. ▪ CTTO confirms acceptable exchanges following additional immunological review and provides appropriate XM reports to the NCC ▪ CTTO confirms with State TTO re-activation of recipients with positive cross-match and the other recipients in the same loop/chain (innocent bystanders) on the NOMS list If proposed matches are confirmed, go to 14.	
14	**Transplant teams notified of matched pairs required for surgical cross matching** AKX Programme Director notifies transplant teams of identified compatible pairs. ▪ NCC sends CD-ROM of donor imaging, CT report, de-identified donor medical information and Surgical Checklist to respective liaison transplant surgeons ▪ Liaison surgeons discuss viability of exchange and potential surgery date, and return completed SC to NCC within 4 working days ▪ If exchange is not accepted, NCC needs to be advised immediately through return of signed SC, noting reason for non-viability of exchange **For ABOi transplant, coordination of surgery dates must occur in consultation with nephrology/haematology department.** If exchange(s) are viable, go to 15.	AKX Surgical Checklist
15	Transplant teams notified of authorised pairs for the exchange. AKX Programme Director notifies transplant teams of the donor/recipient pairs selected for the exchange. De-identified donor information is made available to recipient's centre via MMEx.	Communication via https://mmex.gsmhn.com.au/
16	**Logistics for exchange** AKX Programme Coordinator: ▪ Confirms date of transplants acceptable to Transplant Centres and donor/recipient pairs ▪ Informs the relevant State TT Officers of date of transplants ▪ Identifies responsible person at each site that will oversee coordination of surgical timelines ▪ Identifies the transplant surgeon on site who will assist with donor kidney packaging (if required) ▪ Sends a preliminary transport itinerary to transplant teams to assist with operative scheduling ▪ Reminds centres to action the collection of recipient HLA serum for repeat Luminex single antigen bead (SAB) testing if >2 months since crossmatch was performed	
17	**Transport and packaging resources available** AKX Programme Coordinator sends AKX transport container, trolley and packaging material (AKX Transport Pack) as required. The Transplant Centre ensures AKX Transport Pack is available and checks surgical schedules are in place.	

No.	Action	Relevant document
18	**4 - 2 weeks prior to surgery: Recipient Luminex SAB testing is performed if >2 months since XM** ▪ There may be a delay of several weeks between initial cross-match and surgery, increasing the risk of an adverse immunological outcome. In this instance current serum is retested by Luminex SAB ▪ If any change in Luminex profile a XM will be required ▪ If NO change in Luminex profile a repeat XM is not required. However, it is advisable that the State HLA laboratory verifies with the recipient centre whether a repeat crossmatch is required (this may depend on local hospital policy)	
19	**Consent for surgery and Donor Nucleic Acid Testing (NAT)** The Transplant Centre is responsible for obtaining consent from donors and recipients for the actual surgery as per hospital policy and ensuring that NAT has been performed. The Transplant Centre will organise collection of donor blood samples for NAT at the required pre-surgery interval (Day-9, or as close to this as possible). This test must be required as an URGENT test, and result sent to NCC as soon as available. The NCC will de-identify the NAT result as applicable and forward to recipient centre. If NAT results are negative, go to 20. If NAT results are positive, surgeries will be deferred.	AKX NAT Collection & Algorithm Attachment
20	**Confirm Day of Exchange details** 7-2 days prior to surgery AKX Programme Coordinator confirms with each centre: ▪ AKX Transport Packs have been received ▪ Anaesthetic start times and anticipated pick-up times for organs ▪ Donor Blood request forms for "PKE-store cells" & Living Kidney Donation reports have been received ▪ Copies of de-identified Donor NAT and Blood Group results are available ▪ Name of recipient transplant surgeon who will be present in theatre to assist with packaging (if applicable) ▪ Flight itineraries for organs (as applicable) ▪ Transport Plan, NXF numbers & Consignment Notes for organ transport have been received ▪ Couriers responsible for pickup and delivery ▪ Hospital pickup and delivery points and designated contacts at each hospital ▪ Back-up itinerary and emergency contact details	Day of Exchange Details AKX Organ Transport Itinerary
21	**1 day prior to surgery** 1 day prior to surgery AKX Programme Coordinator: ▪ Checks all items in step 20 are confirmed ▪ Confirms with transplant centres that donor-recipient pairs are fit for surgery (not affected by acute illness, consent not withdrawn)	

No.	Action	Relevant document
22	**Day of surgery** Transplant Centre to confirm, in separate consultations, donor and recipient medical and emotional suitability to participate, letting them know that they can withdraw at any time up until surgery. ▪ If donor and/or recipient withdraw, the Transplant Centre to immediately notify the AKX Programme Coordinator and other Transplant Centre ▪ The Transplant Centre to notify the AKX Programme Coordinator immediately of any last minute issue regarding consent, packaging, transport and surgery ▪ For donor surgery, ensure Donor blood samples, hard copies of de-identified Blood Group and NAT results and completed sections 1 and 2 of the Living Kidney Donation Report accompany the kidney ▪ For recipient surgery, ensure the kidney received is cross-checked and correct for the recipient prior to implantation	Living Kidney Donation Form
23	**After transplantation** The Surgical Team to complete section 3 of the Living Kidney Donation Report and forward to AKX Programme Coordinator within two working days of procedure.	Living Kidney Donation Form
24	**Post Transplant Notifications** The AKX Programme Coordinator: ▪ Completes NOMS renal transplant notification forms and sends to CTTO (for distribution to relevant state labs) and ANZDATA ▪ Requests recipient and donor post transplant data (discharge creatinine) and feedback re any issues ▪ Completes ANZDATA Living Donor Forms (recipient details are inserted) that have been received from transplant centres and forwards to ANZDATA Transplant Centre ▪ Completes ANZDATA Living Donor forms and forwards to AKX Programme Coordinator for completion of recipient details ▪ Provides post-transplant information/feedback as requested by NCC	
25	**Data collection** The NCC collects data on the outcome of the transplants and reports annually to the Organ & Tissue Authority.	

Guidelines for the Evaluation of Living Donors for the AKX Programme

The purpose of these guidelines is to define the appropriate information and/or investigations that must be completed for consideration for entrance into the Australian Paired Kidney Exchange Programme (AKX). The referring unit is primarily responsible for ensuring the safety and the well-being of the donor.

AKX does not evaluate donor suitability but rather confirms that the respective Transplant Centre has evaluated and accepted the donor(s) as a suitable candidate. The unit that will perform the donor surgery undertakes the testing and assessment of the donor in accordance to the unit protocol; this usually involves a multi-step process and the suggested steps outlined in this document are simply a guide and by no means an AKX directed process. The assessing team is responsible for ensuring that the potential donor is in good health, has normal kidney function and structure and is not a risk to the recipient with respect to transmission of viral or other infections.

The recipient's team must be reasonably satisfied that the organ they receive for their patient is of equal (or superior) quality to the standards used at their centre.

AKX must provide some key information to the recipient's team on relevant clinical features of the donor that might materially affect the outcome of transplantation. This information should be discussed with the recipient, in a generic manner to avoid identification of the donor, to obtain informed consent.

To record and audit this information a purposely-designed electronic donor record using the Medical Message Exchange (MMEx) portal has been specifically developed for AKX.

Registration data for MMEx does not include ALL of the following tests, but it is expected that donor suitability assessment must be carried out according to these accepted criteria. The constraints with regard to donor suitability that are built into the MMEx registry and won't allow a donor to be registered are listed in Table 1.

Step 1: Initial evaluations required prior to registration in AKX Programme

The following information can be collected and the necessary investigations requested at the **first visit** with the nephrologist.

A. Medical history and physical examination including:

- Age
- Gender
- Height, weight (BMI), blood pressure and heart rate
- Relationship to the potential recipient
- Reason for incompatibility (ABO or positive crossmatch)
- History of hypertension (no/yes), on current medication (no/yes)
  If yes, number of drugs (1, 2, ≥3)
- Glycaemic status: impaired fasting glucose (no/yes), impaired glucose tolerance (no/yes)
- History of malignant cancer (no/yes)
- History of renal stone disease (no/yes), if yes, recurrent (no/yes), if yes, when last?

B. Blood tests:

- Blood group (Group A donors are required to be subtyped), UEC, LFT, BSL, FBP with differential, coagulation profile

C. Urine tests:

- Urinalysis and culture, urine protein/creatinine ratio or 24hr urine protein excretion.
  MMEx has scope to accept only urine PCR (<30 mg/µmol) or 24hr protein (<300mg/24h) values

D. Virology:

- CMV, EBV, HIV, HBV (including Hep B core antibody) & HCV, Syphilis

E. Other tests:

- Renal Ultrasound, CXR
- ECG

Step 2: Additional evaluations required prior to registration in AKX Programme

The following information can be collected at a **subsequent visit**, if the donor has satisfied the initial suitability criteria after the first assessment.

F. Tissue typing:

- HLA typing as per agreed criteria – refer AKX Tissue Typing Guidelines

G. Renal function and anatomy:

- CT Angiogram – refer to Attachment 4a for recommended guidelines
- Radioisotope GFR as measured by appropriate technique must be ≥80 ml/min
  - Method must be 51Cr-EDTA or 99Tc-DTPA by slope-intercept technique

A radioisotope GFR of at least 80 ml/min has been agreed to satisfy the minimum requirement of acceptable quality of the donated kidney. The GFR value is an absolute value and NOT per body surface area, as it is a measure of the adequacy of the kidney for a recipient, not the safety for its removal from the donor which has been assessed separately.

- Renal scintigram technique to assess split renal function
  - Split function range should be 45% - 55%, if nGFR<100

The combination of radioisotope GFR and nuclear split function criteria eliminate the potentially perceived bias that two donor kidneys may differ because of age and body size and, as such, exchanges could not be considered "equal". A split function <45% - >55% is not an exclusion of donor acceptance, as long as the single kidney function of the donated organ is satisfactory (predicted GFR ≥40ml/min).

H. Cancer screening:

In individuals aged >50 years:

- Bowel cancer testing kit
  - Faecal Occult Blood (FOB) x 3 **or**
  - Colonoscopy if this is part of the individual's normal screening regime (eg. known family history of Bowel cancer)

Women aged >50 years:

- Pap smear and mammogram
  - If patient has had a hysterectomy please note this on MMEx in the field provided, with the date of hysterectomy (as close to date as possible if actual date not known)

Step 3: Additional evaluations prior to registration in AKX Programme

I. Mandatory specialists consults:

- Surgical evaluation
- Psychosocial evaluation according to normal unit practice

J. Optional investigations / consults:

- Cardiology consult as indicated
- Pulmonary function tests if donor has significant smoking history/COPD

All of the above assessments must be completed prior to activation on the AKX Programme.

Step 4: Annual nephrology review/tests required for maintenance on Programme

- Medical history/physical examination/updated medication list
- UEC, LFT, BSL, FBP
- HIV, HBV, HCV, Syphilis, and CMV/EBV as indicated (not necessary to repeat if previous positive CMV or EBV serology)
- Urinalysis/protein-creatinine ratio
- Other consults as indicated
- Cancer screening at applicable intervals for individuals >50 years
  - Pap smear every 2 years
  - Mammogram at least every 5 years
  - Colon cancer screen every 5 years

Confirmation of compliance with these tests and reviews at each 12-month anniversary of entry into AKX must be provided to the Program Coordinator by the local transplant unit.

This is done by updating the following as applicable on the donor MMEx registry:

- Creatinine level
- HIV, HBV, HB core antibody, HCV and CMV/EBV
- 24hr urinary protein OR protein-creatinine ratio
- Cancer screening
- Annual review date

Table 1: Donor suitability constraints preventing registration of potential donors in the AKX Programme

---

Medical history and physical examination including:

Age - *The system will not accept a donor older than 70 years of age*

History of hypertension - *The system will not accept a registration for any donor with treated hypertension on ≥3 drugs*

Glycaemic status - *The system will not accept a registration for any donor with diabetes*

History of malignant cancer[1] - *The system will not accept a registration for any donor who had a previous history of cancer other than: Colon cancer Dukes A >5 yr ago, Non-melanoma skin cancer, Carcinoma in situ of the cervix*

History of renal stone disease[2] - *The system will not accept a registration for any donor who had a previous history of recurrent renal stone disease*

Laboratory testing:

Proteiniuria - *The system will not accept a registration for any donor who has urine protein/creatinine ratio >30 mg/mmol or 24hr protein >300mg/24h*

Virology[3] - *The system will not accept a registration for any donor who tests positive for HIV, Hepatitis B surface antigen, isolated Hepatitis B core antibody, or Hepatitis C antibody*

Renal function and anatomy:

CT angiogram - *The system will not accept a registration for any donor with 3 renal arteries or 2 renal artery one of which has early branching <15mm from the aorta on both sides*

Radioisotope GFR - *The system will not accept a registration for any donor with nGFR <80ml/min not corrected for BSA*

---

[1] For some other malignancies the risk of donor derived transmission is sufficiently low to be considered acceptable for live kidney donation. This applies for malignancies with a <0.1% risk of transmission events/organ transplants from donor with specific tumor. We refer to AST guidelines for the suggested risk categorizations for specific tumor types (Nalesnik et al, AJT 2011; 11: 1140–1147).
Use of higher risk donors (>0.1% risk of transmission) is discouraged and should only be considered in recipients at significant risk without transplant and would require informed consent. This would not be acceptable in the AKX Programme.

[2] The decision to define whether the donor is a recurrent stone former is left to the discretion of the donor team. The natural cumulative recurrence rate of renal stones is reported to be 14% at 1 year, 35% at 5 years, and 52% at 10 years (Uribarri et al., Ann Intern Med. 1989; 111:1006-9). It would seem prudent not to accept those with high rates of recurrence, such as those with cystine or struvite stones. In addition, those with systemic disorders that lead to high rates of recurrence, such as primary or enteric hyperoxaluria, distal renal tubular acidosis, sarcoidosis, inflammatory bowel disease, or other conditions that cause nephrocalcinosis etc., should not donate.

[3] HBsAg negative patients who are:
- anti-HBc positive and anti-HBs positive are considered immune due to natural infection and are acceptable.
- anti-HBc positive and anti-HBs negative may have “low level” chronic infection or resolving acute infection and are not acceptable as donors.
(MMWR 2005;54 (No. RR-16) www.cdc.gov/hepatitis)

Tissue Typing Laboratory (TTL) Guidelines for the AKX Programme

This document briefly outlines the Tissue Typing Laboratory requirements to enable implementation of the AKX Programme.

Acronyms referenced in these Guidelines

CTTO = Coordinating Tissue Typing Officer
NCC = National Coordination Centre
TTL = Tissue Typing laboratory
DSA = Donor-Specific Antibody
MFI = Mean Fluorescence Intensity
SAB = Single Antigen Bead
APMM = Authorised Previous MisMatch
IPMM = Ignore Previous MisMatch
OLI = One lambda Inc. (antibody assay)
Tepnel = Lifecodes Immucor Inc. (antibody assay)

Introduction

The AKX Programme uses a sophisticated algorithm to find matches among the pool of incompatible donor-recipient pairs to create simultaneous 2-way, or 3-way exchanges, or more complex non-directed donor chains of transplants. The algorithm matches each recipient's HLA antibody against each of the donor's HLA antigens. First, matched pairs are found by comparing the ABO blood groups of each donor and each recipient, then by checking the donor specific antibodies (DSAs) of recipients and comparing these in turn with the HLA-typing of each ABO compatible donor. The acceptable matches are identified by excluding donors with HLA alleles to which a particular recipient has DSA with a default reactivity of >2000 MFI for both class I and class II HLA alleles.
These guidelines outline the requirements and processes necessary to achieve the goal of the AKX Programme.

1 HLA typing requirements for donors and recipients

1.1 HLA typing requirements for donors

For donors all loci are required to be at 4-digit level[#]. For entry onto the AKX register, donors must have an authorised HLA typing recorded into the NOMS for each of the following mandatory HLA loci:
HLA-A*, HLA-B*, HLA-C*, HLA-DRB1*, HLA-DPB1*, HLA-DQA1*, HLA-DQB1* and HLA-DRB3/4/5*.
[#] HLA-DQA1 and –DRB3/4/5 typing are required to be at 2-digit level minimum, although typing at 4-digit level resolution is always encouraged where available.

1.1.1 Overseas Donors

Recipients with Australian citizenship are able to be co-registered with a donor who resides overseas if the following conditions are met:

- The donor is reviewed by the Australian unit prior to registration
- HLA typing is performed in Australia to AKX specifications
- Adequate blood is obtained at time of sampling to enable freezing of cells for later use e.g. crossmatch.
- TTL to verify that a sufficient number of cells are isolated from this sample to enable multiple crossmatches to be performed. If necessary recall donor for additional specimen (in case donor returns to home country prior to match run)
- The donor is able to accommodate any potential surgery timeline.

1.2 HLA typing requirements for recipients

For recipients (new and existing) all loci typing at 4-digit level is encouraged. For entry onto the AKX register, patients must have an authorised HLA typing recorded into NOMS for each of the mandatory HLA loci (cf deceased donor list):
HLA-A*, HLA-B*, HLA-C*, HLA-DRB1*, HLA-DPB1*, HLA-DQA1*, HLA-DQB1* and HLA-DRB3/4/5*.
Full typing of recipients is required for the purposes of epitope matching and to exclude the possibility of self-reactive antibodies, particularly for DP locus.

1.3 Donors that express an HLA allele not included in one of the single antigen bead assays

Currently NOMS is unable to exclude from matching recipients with donor-specific antibody (DSA) against a donor expressing a 4-digit HLA allele that is not covered by the Single Antigen Bead (SAB) assays. For this reason if a donor expresses a 4-digit HLA allele that is not covered by one of the SAB assays, special management procedures are required (e.g. C*07:01 is not currently included in the One Lambda Inc. (OLI) kit).
Prior to each match run the state tissue typing scientist will be responsible for:

1.3.1 Supplying the CTTO with the HLA type of all the donor(s) they have entered into the AKX match run with any HLA alleles not covered by the SAB assay highlighted

1.3.2 Circulating the list of alleles included in the two SAB platforms used by the different TTL prior to each run

1.3.3 Entering the following comment into the NOMS donor record for each donor expressing an HLA allele that is not covered by the SAB assay
- "**Following alleles are not represented in the current OLI/Tepnel SAB lot: (e.g.) B*35:02, DRB1*08:03".**

1.4 HLA nomenclature

Whenever possible the 4-digit molecular nomenclature (describing a specific allele of the antigen) will be used for HLA antigens and HLA-antibodies used in the NOMS database for the purpose of the AKX programme.

In exceptional circumstance information may only be available based on historical data obtained by serological typing. This could be the case if a patient had a previous transplant and HLA specificities for the previous donor are only available at the 2-digits resolution to describe an antigen. In rare instances a patient may have a record of a historical HLA antibody demonstrated by serological methods, but the historical serum is no longer available to determine 4-digit specificity by Luminex SAB (see 5.1). In this instance the unacceptable antigen(s) based on the specificity of the serological antibody should be authorised in the APMM register (see 3.1).

As the 2 digit antigens will generally be identical to the first two digits of the four digit alleles, the few exceptions to this rule will need to be listed in the NOMS HLA antigen/allele relationships table exclusively using 2-digit molecular nomenclature. All the required antigen and allele code updates must be validated by the TTL.

Examples:	4-digit molecular	2-digit molecular	2-digit serological
	A*11:01	A*11	A11
	C*03:04	C*03	Cw10
	DRB1*03:01	DRB1*03	DR17

2 HLA antibody screening of patients

For entry onto the AKX register, patients must have an authorised antibody record tested by one of the Luminex SAB test providers (OLI or Life Technologies) for both Class I and Class II HLA antibodies.

Patients newly registered on the programme and not previously antibody tested must have SAB testing performed and then confirmed within 3 months prior to the run. Confirmatory SAB testing must be performed using a sample collected at least one month later than the initial sample.

Individual antibody strengths expressed as mean fluorescence intensity (MFI) must be entered into the record (with reference to defined ranges listed in the code table) for all Luminex-detected Class I and Class II HLA antibodies.

Authorised antibodies to be used in defining unacceptable mismatches are assigned by each State TTL in consultation with their clinicians. These should, in general, be the level which is likely to give a positive CDC crossmatch, ie >2000MFI for OLI >1500MFI Tepnel. By using these cut offs we would expect that the CDC crossmatches will almost always be negative and thus prevent a donor chain from "falling over".

Antibody results at the **4-digit** level are required to be stored in NOMS along with MFI values for all authorised and unauthorised antibodies detected by SAB assay.

2.1 Testing frequency

For patients already registered in AKX and entered in previous match runs, testing should be repeated:

- every 6 months if antibodies are detected or if they had a previous failed transplant
- every 12 months if they are non-sensitised, first transplant candidates and no antibodies are detected

All patients must be tested by SAB assay after any sensitisation event AND if matched in a run (testing at the time of crossmatch).

2.2 HLA antibody strength

Published data indicates that in the presence of DSA, values of <2000MFI (by OLI kit) are unlikely to yield a positive **CDC-crossmatch**, whereas >8000MFI are extremely likely to have a positive CDC crossmatch. The cut-off for a positive **flow cross match** is somewhere around 1000 – 2000MFI and certainly a value below this is unlikely to have a positive flow cross match. Generally, levels from 1000 to 2000MFI are considered weak and most clinicians would not exclude transplant candidates to accept a kidney from a donor in the presence of a weak DSA in this range. Such antibodies are likely to be biologically relevant and should be interpreted in relation to other information (e.g. mismatched antigen in a previous donor or an antigen present in the patient's offspring etc.) and some physicians might monitor more carefully or modify the pre or post transplant immunosuppression.
A review of the Asia Pacific Histocompatibility and Immunogenetics Association (APHIA) QC data has suggested that in general Tepnel has lower MFI and that a value of 1500MFI is the equivalent of a 2000MFI for OLIand using such cut -offs will result in very similar calculated panel reactive antibody (cPRA) amongst all TTL.

3 Additional considerations in the definition of unacceptable HLA antigens

Previous transplant data should be entered into the NOMS database with the HLA typing authorised by the State TTL. The following describes how the entry of previously transplanted mismatched antigens works:

◊ It is the responsibility of State TTL to enter previously transplanted mismatched antigens in the Authorised Previous MisMatch (APMM) register.
◊ All previously transplanted mismatched antigens must be entered.
◊ Clinicians, following discussion with the TTL, may deem it safe to remove a previously transplanted mismatched antigen from the authorised mismatches (because of current and historical absence of a specific antibody to the previous mismatch).
◊ In this case the antigen must be entered into the Ignore Previous MisMatch – PKE (IPMM) register. This register must be checked and authorised by a second NOMS user.

3.1 Exclude previous MisMatches

Previously transplanted mismatched antigens will by default be considered in the organ matching process unless otherwise agreed between clinicians and the local TTL. Previously transplanted mismatched antigens will result in exclusion of a potential donor bearing any of the previous mismatches listed in the APMM Register.

◊ Clinicians, in consultation with their TTL, may decide to enter any other unwanted antigens into the APMM register. Examples for this strategy are
  - incompatible spousal live donor pairs, where the donor is the husband and one or more specific antigens of the husband need to be excluded (for instance because of presence of DSA <2000MFI to husband antigens).
  - exclusion of antigens where the predicted eplet load would be exceedingly high in case of a match, even if no antibodies to that antigen are detectable.

3.2 Ignore previous MisMatches

Any previous mismatched transplanted antigens that are deliberately not considered for exclusion in the matching process must be entered in the IPMM Register.
An IPMM register antigen will result in a recipient not being excluded for a donor bearing the IPMM-listed HLA antigen. The IPMM register can be used to remove a previously transplanted mismatched antigen from the authorised mismatches, because of current and historical absence of a specific antibody to the previous mismatch.

e.g. Recipient HLA A*03:01,*31:01, previous donor HLA A*03:01,*02:01, Luminex SAB no DSA A*02:01 >500MFI in peak or current sera. Entering A*02:01 in the IPMM register will result in any AKX donors with HLA-A*02:01 not being excluded from matching to this recipient.

3.3 Molecular equivalents of previous serological HLA types

The APMM register of authorised HLA antigens must be the molecular equivalent of the donor's serological HLA types which were authorised at the time of the previous transplant. The HLA antigen data should be entered as 4-digit.

- ◊ Patients with a failed transplant from a previous donor should preferably have molecular typing of the previous donor where possible. The TTL will enter a common list of unacceptable antigens (2-digit) to be entered as molecular equivalents for this purpose,
- ◊ Where the existing previous donors' authorised antigens are available only as serological types, The TTL will enter a common list of unacceptable antigens (2-digit) to be entered as molecular equivalents for this purpose.
- ◊ The organ matching for a patient will exclude any donor bearing any of these antigens.

4 ABO-incompatible register

Given the excellent outcomes of ABO-incompatible transplantation in the absence of DSA, an additional strategy to increase options for sensitised patients is to accept kidneys from ABO-incompatible, but HLA acceptable donors within the existing AKX pool. The acceptance of ABO-incompatible donors for some of the highly sensitised recipients in the AKX program results in a "virtual" expansion of the donor pool. While the actual pool size is unchanged by allowing ABO-incompatible matching, permitting more exchanges within the same pool increased the match probability. This strategy has been already applied successfully in the AKX programme.

The TTL is required to enter a row in the IPPM-ABOi register with individual donor blood group acceptance (A, B or AB). The referring transplant unit is responsible to determine whether acceptance of an ABO-incompatible donor is a feasible option for their recipients. AB donors are not accepted for O recipients.

Recipient Blood Group	Transplant Unit referral			NOMS Register Entry
	Accepts A	Accepts B	Accepts AB	
O	yes	yes	Not accepted	A,B
O	no	yes	Not accepted	B
O	yes	no	Not accepted	A
A	-	yes	yes	B,AB
B	yes	-	yes	A,AB

5 Method of matching by NOMS for AKX

The NOMS PKE program will match:

1) recipients HLA antibody *against*
2) donors HLA antigens using 2 main principles:
   - maximise the number of suitable donor-recipient pairs using match probability (to exclude unacceptable mismatches)
   - maximise number of blood group ABO identical pairs (ABO identical > ABO compatible).

The Match Probability (MP) will be calculated as: MP = (a/b), where:

a = the number of acceptable donors in the run (i.e. donors having no HLA antigens to be excluded because of patient DSA or previously transplanted antigens)

b = total number of ABO compatible/acceptable donors in the run.

MP range is 0 to 1: 0 implies no compatible donors and
1 implies all ABO compatible donors are suitable matches.

Recipients HLA antigens are not used for the purpose of matching.

5.1 Method of matching patient antibody against donor HLA

The default method of matching will be to match 4-digit patient antibody to 4-digit donor HLA:

◊ A 4-digit patient antibody specificity will result in exclusion of any donor with that precise allele authorised in the HLA typing. However donors with any authorised other allele of the antigen will not be excluded. This will enable a crossmatch to be performed.

Acceptable matches are identified by excluding donors with HLA alleles to which a particular recipient has donor-specific antibody (DSA) with a default reactivity of >2000 MFI for both class I and class II HLA alleles in the authorised serum.

Cut-offs for One Lambda Inc. (OLI) Luminex assay are as follows:

To be entered in NOMS by default as unauthorised, i.e. **do not exclude from matching**.

- Weak 500 – 2000

To be entered in NOMS by default as authorised, i.e. **will exclude from matching.**

- Moderate 2000 to 8000 or Strong >8000

Cut-offs for Lifecodes Immucor Inc. ('Tepnel') Luminex test are as follows:

To be entered in NOMS by default as unauthorised, i.e. **do not exclude from matching.**

- Weak 300 - 1500

To be entered in NOMS by default as authorised, i.e. **will exclude from matching.**

- Moderate 1500 to 4000 or Strong >4000

5.2 Selection of authorised serum to be used for the match run

Evidence suggests that the current serum (actual PRA) may underestimate true sensitisation and post-transplant immunological risk. The default serum authorised for match run is the patient's peak serum (peak PRA), unless otherwise advised by the recipient's team.

It is acknowledged that the amount of one antibody may be high in one serum sample and another antibody may be higher in a different serum sample. In this instance, if a clinician is of the opinion that an antibody not present in the peak serum should be authorised for the purpose of matching, it is suggested that this antibody is entered in the APMM register (see 3.1).

Ultimately, the selected panel of antibodies authorised for the match run is at the discretion of the patient physician in combination with the local state TTL.

5.3 Advantages and limitations of a rigid arbitrary MFI cut-off

MFI levels on the beads represent the amount of antibody bound relative to the total antigen present on the beads, which varies by individual bead. The MFI has been used successfully to predict flow cytometry or CDC crossmatch results and is particularly useful in predicting negative crossmatches.
In the AKX programme the approach of using a default reactivity of >2000 MFI has been shown to result in nearly 99% of identified matches having a negative cell-based crossmatch. However, this high sensitivity comes at a cost of a low specificity, because it is less reliable with low levels of antibody. Some Luminex positive patients with DSA above the default threshold used for exclusion of matching could potentially have a negative cell-based crossmatch, as well as good medium to long-term outcomes.

5.4 Individualised assignment of unacceptable HLA antigens

In the AKX programme a high proportion of the incompatible pairs are enrolled as a result of HLA-incompatibility. Some highly-sensitised recipients with broad sensitisation have only a limited number of rare donor HLA genotypes that they can source and this leads to the accumulations of patients with broad sensitization and high antibody strength against common antigens in the AKX pool. Alternative allocation strategies are required to assist these patients and one possible solution is the individualised assignment of unacceptable HLA antigens.

There are several arguments to suggest that this is a reasonable and safe approach:

- The relative quantity of a particular antigen on Luminex beads differs among pooled antigen phenotype and SAB. For instance, some panels are characterised by a higher relative antigen density of HLA-C, HLA-DQ, and HLA-DP on SAB. Therefore, antibody levels to these antigens while representing only a low immunologic risk for allograft rejection will be overestimated.
- Some of these HLA loci are expressed in vivo at lower level (C and DP) and thus a higher MFI cut-off value may result in a negative CDC-crossmatch and a negative or weak-positive flow cytometry crossmatch.
- In highly-sensitised recipients, HLA-antibodies with lower MFI values may be selectively ignored, giving the patient an opportunity to have a cross-match performed in which the result may be acceptable despite the presence of a DSA.

Therefore, there may be instances where a transplant team decides to deliberately allow some HLA antibody specificities with >2000MFI in a particular patient. This means that donors with HLA alleles to which a particular recipient has donor-specific antibody (DSA) with a reactivity of >2000 MFI will not be excluded from matching with this recipient.
For these cases a recipient evaluation form outlining HLA antibody to be ignored (see appendix) should be made available to the CTTO and NCC.
If DSA >2000 MFI are present in non-authorized sera the patient's physician will be notified after the potential match is identified, before a chain is offered for consideration to all centres involved.

The individualised assignment of unacceptable mismatches should consider the sensitisation status of the patient:

- Patients with a cPRA <75% are very likely to find a compatible donor in the AKX pool with no DSA to the matched donor.
- Patients with cPRA >75% (highly-sensitised) and in particular those with cPRA >95% are less likely to find a compatible donor in the AKX pool with no DSA to the matched donor.

It is suggested that individualised assignment of unacceptable mismatches should be reserved for highly-sensitised recipients.
The selection of the best available compatible donor with the longest projected graft lifespan should be considered for those likely to require retransplantation. Therefore, it is also possible to consider excluding 'acceptable' mismatches (where there would be no DSA to a specific donor HLA antigen) for patients with narrow sensitisation, in particular paediatric patients and young adults. In this instance one or more specific alleles can be listed in the APMM Register (see 3.1).

6 Further testing after a match run

6.1 CDC-crossmatching

CDC crossmatching is the cell-based immunological assay that will satisfy the requirements to safely proceed with live donor kidney transplantation in the majority of cases where no DSA or only weak DSA between recipient and matched donor are present. Based on the APHIA Consensus and the AKX experience with the first 100 matched pairs, DSA with MFI values of <2000 (by OneLambda) are unlikely to yield a positive CDC-crossmatch.

6.2 Flow cytometry crossmatching

Flow crossmatching is not performed routinely for AKX matched pairs, however flow cytometry crossmatching (FCXM) is available. It is suggested that FCXM be considered for all matched pairs with single or cumulative DSA > 2000MFI . The decision to perform FCXM rests solely with the patient's physician. If required, FCXM should be arranged with the appropriate laboratory to be performed at the same time as the CDC crossmatch. These results should be used to stratify immunological risk rather than as a decision making tool to exclude or accept matching.

Occasionally, non-specific positive CDC crossmatches in the absence of DSA can be observed. In these rare circumstances FCXM should be considered to determine whether it is acceptable to proceed to transplantation.

6.3 Allocation of a non-directed donor chain kidney (last in chain) to the transplant waitlist recipient

When a non-directed donor (NDD, also known as altruistic donor) is referred to AKX and starts a chain of transplants, the last recipient in the chain will have a living donor who has not donated during the match cycle. This donor will donate to the deceased donor list (and close the chain) of the State that submitted the NDD donor to AKX. Allocation of the last donor in the chain to the State-of-origin waitlist will follow the standard NOMS allocation rules for deceased donors.

The timing of the allocation will be as close as possible to the scheduled date of surgery planned for the NDD chain. However, the timing must take into consideration the need for the recipient State to prepare trays with sera of potentially blood group compatible waitlist recipients, send trays to donor's TTL, recall of the donor to provide cells for crossmatching, perform the actual CDC-crossmatch and prepare a report for the recipient's team.

The unit performing the transplant of the waitlist recipient will also need sufficient time to assess/ review intended recipient medical suitability and for the laboratory to repeat a Luminex SAB test on a current serum, as there could be patients on TWL who have screening results up to 12 months previous as these are generally reviewed annually unless the labs have been notified of a sensitising event.

It is therefore suggested that allocation should take place no later than 3 weeks prior to the scheduled date for the NDD chain surgeries. Possibly a shortlist of 3 possible recipients should be made in case a contraindication comes to light clinically or immunologically within that 3 weeks time frame.

6.4 HLA antibody testing after matching and prior to transplantation

Following a successful match ideally transplantation should occur as quickly as possible and preferably prior to the subsequent match cycle. In the event of surgical delay (> 2 months since match run) HLA antibody testing should be performed within 4 weeks prior to scheduled surgical date. If the SAB profile has not altered significantly then a repeat CDC crossmatch is not required. If a repeat CDC crossmatch is required, based on altered SAB profile or physician request, then CDC crossmatching should be performed 7 days prior to scheduled surgical date.

7 Coordination of tissue typing work

The Coordinating Tissue Typing Officer (CTTO) is responsible to track all the necessary steps of the tissue typing process and provide updates to the NCC, these include:

1) confirmation of completion of tissue typing of donors and recipients referred to AKX,
2) post-run review of recipient's antibody record against matched donor to ensure no authorised DSA have been missed,
3) coordination of crossmatch test dates ,
4) review of crossmatch results and generation of crossmatch reports (donor de-identified and recipient de-identified),
5) distribution of reminders to State TTL for SAB retesting of matched patients, as required.

Following a match run the CTTO is responsible to ensure with the State TTL that patients in matched pairs are temporary off-listed from the NOMS deceased donor waitlist. This will usually occur on the day a NOMS allocation has been executed and a combination report was generated. It will generally include all patients matched in the top ranked combination, unless any obvious mistake is evident upon first review of the combination reports.

Transplant candidates who are temporary off-listed will be reactivated in the NOMS waitlist on the advise of the CTTO in consultation with the NCC when:

1) A patient has an authorised, but unacceptable DSA identified following the post-run review of the patient antibody record that was missed in the computer allocation (e.g. donor HLA allele that is not covered by one of the SAB assays).
2) The referring team refuses a match offered to one of their recipients (e.g. the team would accept ABOi donor, but no DSA or specific DSA, but only if ABOc donor).
3) A patient has final positive cell-based crossmatch result to the matched donor (in this case the other patients in the same chain will be reactivated on the waitlist).
4) A chain breaks down because of recipient or donor unsuitability reasons.

If the date of surgery for pairs in one chain following a match run is scheduled after the subsequent match run, these pairs will remain temporary off-listed.
If the date of surgery for pairs in one chain is unexpectedly delayed because of acute illness in one of the recipients and can't be rescheduled prior to the subsequent match run, the NCC will advise the CTTO if patients in the chain will be reactivated on the waitlist and pairs entered in the next match run.

8 Protocol for orphaned kidneys and recipients

8.1 Definitions

Orphaned kidney: refers to a kidney removed from an AKX donor that cannot be transplanted into the matched recipient.

Orphaned recipient: refers to an AKX recipient whose co-registered donor has donated, but who has been unable to receive a kidney from the matched donor.

The protocol for orphaned kidneys and orphaned recipients has been developed by the National Paired Kidney Exchange Programme Advisory Group[1] and revised as required by the AKX Oversight Commitee[2].
In the rare event where an exchange cannot proceed due to unforeseen clinical or logistical circumstances, the following is recommended:

[1] National Paired Kidney Exchange Programme Advisory Group: An advisory group of the National Cognate Committee on Organ & Tissue Donation & Transplantation, Page 18-19.
[2] AKX Oversight Committee: OTA , AKX Programme Director & RTAC Chair

8.2 Orphaned kidney

On the day of transplant surgery a recipient may suffer an acute event immediately prior to going to theatre, during induction or during their operation such that the procedure needs to be abandoned. Because donor surgery always occurs before recipient surgery, the donor has already had their kidney removed. This will result in an 'orphaned kidney'.

Donors are asked to consider in advance whether, in this rare circumstance, they would be willing for their kidney to be allocated to someone suitable on the deceased donor transplant waiting list. It is precisely for this unlikely, but possible, contingency that a specimen of donor's whole blood (40ml) is taken at anaesthetic induction and transported with the kidney.

8.2.1 Process for determination and allocation of an orphaned kidney

Recipient Centre: must immediately notify the AKX NCC if the recipient has become acutely ill and is unable to undergo or continue with transplant surgery.

Steps for allocation of an orphan kidney:

- The NCC will determine current location of orphaned kidney:
  - If kidney is in transit, the state of destination will be the beneficiary of the incoming kidney
  - If kidney is still in the state of origin, it will be allocated to a transplant waiting list recipient within this state
- The NCC will alert the CTTO to perform an urgent NOMS search / virtual crossmatch to identify a suitable recipient
- The CTTO will generate a NOMS allocation list
- Virtual crossmatch will be performed by the CTTO using the AKX matching criteria and the top 5 state recipients
- The CTTO will notify the NCC about the identified potential match (State of origin or State of destination) and the transplanting centre under which the identified recipient is listed
- The NCC will contact recipient's transplant centre to alert of the probable allocation. The de-identified MMEx live donor report will be made available to the recipient's team
- The CTTO will alert relevant TTL to prepare for an urgent cross-match test
- The state TTL will perform CDC crossmatching against the top 5 recipients. This information may be provided to the physician retrospectively if necessary
- The TTL performing the crossmatch will send a report to the recipient's centre, with copy to the NCC and CTTO
- The NCC will ensure the waiting list recipient centre has been duly informed
- The NCC will report the critical incident to the OTA/AKX Oversight committee and monitor outcomes
- The NCC will facilitate communication of the resultant issues and outcomes between donor and recipient centres as required

8.3 Orphaned recipient

There may be multiple reasons for this eventuality, some of which are:

- donor nephrectomy could not be completed due to donor becoming acutely ill during surgery
- kidney was lost in transit or the wrong kidney was delivered
- kidney received by transplanting hospital was damaged during transport or packaging is found to be inappropriate
- kidney received by transplanting hospital could not be transplanted due to surgical issues
- recipient is acutely unwell and cannot undergo transplant surgery (see 'orphan kidney')

The outcome is that the intended recipient cannot receive a kidney, and is therefore an 'orphaned recipient'. The recipient's co-registered donor has already donated his/her kidney and thus the recipient no longer has recourse to an exchange.

In this situation, the 'orphaned recipient' will receive NOMS priority listing (Level 3-4 interstate exchange) for a suitable kidney from the National deceased donor organ pool.
Pre-emptive recipients are not listed in NOMS, as activation on the deceased donor waitlist starts with the first day on dialysis. In these cases, exception will be made after notification and approval by RTAC that the pre-emptive recipient can be listed for priority allocation on the NOMS deceased donor waiting list.

IMPORTANT: if a kidney is transplanted and kidney reperfusion has been established, the recipient will not be considered an orphan recipient, even if the kidney never functioned.

The Donor and Recipient Agreement to Participate form expressly addresses "orphan kidney" and "orphan recipient" eventualities, which must be discussed during the consent process, and clearly understood by the potential donor and recipient pairs.

Agreement to participate and Ministerial Approval Process

The process for seeking donor and recipient agreement to participate differs in each jurisdiction based on legal requirements. The Agreement to participate and Ministerial Approval is outlined below by jurisdiction.

QLD and VIC

Agreement to participate

QLD and VIC Local Transplant Centres:

- ◊ Obtain signed Agreement to Participate Forms for the donor and recipient pair to participate in the AKX Programme.
- ◊ Submit the Signed Agreement to Participate Form to the National Coordinating Centre via fax, post, email or MMEx upload

Ministerial Approval

Ministerial Approval is not required for donors and recipients in Queensland and Victoria as AKX does not contravene Human Tissue Acts in these jurisdictions.

NSW/ACT/TAS/WA

Agreement to participate

Local Transplant Centre to:

- ◊ Obtain signed Agreement to Participate Forms for the donor and recipient pair to participate in the AKX Programme.
- ◊ Submit the Signed Agreement to Participate Form to the National Coordinating Centre via fax, post or email (scanned copies are acceptable).
- ◊ Once the Agreement to Participate is obtained, Ministerial Approval is required before the donor and recipient pair can be activated on the MMEx registry.

Ministerial Approval

Steps for obtaining Ministerial Approval:

1. Local Transplant Centre to complete Section 1 of the Ministerial Approval Form and fax, or scan and email the completed approval form to the AKX Programme Coordinator. The original is NOT required as long as the fax or scanned copies are clear and legible.
2. AKX Programme Coordinator to complete Section 2 of the Ministerial Approval form.
3. AKX Programme Coordinator to send Approval Forms/Briefing Note to the relevant State Health Department.
4. Health Department Representative to forward Approval Form to the Minister for Health/Chief Health Officer or Delegate.
5. Minister for Health/Delegate to complete Section 3 of the Ministerial Approval Form and return the signed form (scanned and emailed) to the National Coordinating Centre within 5 working days of receiving the form.
6. National Coordinating Centre to scan and upload a signed copy of the approval form onto the MMEx and also forward a copy to the Local Transplant Centre via email.

    - ➢ **Note that ACT participants also require approval from NSW Chief Health Officer as surgery will be performed in NSW.**

SA/NT

Ministerial Approval

In SA and NT, Ministerial Approval must be gained before the Agreement to Participate Form is signed.

Steps for obtaining Ministerial Approval:

1. Local Transplant Centre to complete Section 1 of the Ministerial Approval Form and fax, or scan and email the completed approval form to the AKX Programme. The original is NOT required as long as the fax or scanned copies are clear and legible.
2. AKX Programme Coordinator to complete Section 2 of the Ministerial Approval form.
3. AKX Programme Coordinator to send Approval Forms and Briefing Note to the State Health Department.
4. SA Health Department Representative to forward Approval Form and Briefing Note to the Minister for Health.
5. Minister for Health to complete Section 3 of the Ministerial Approval Form and return the signed form (scanned and emailed) to the National Coordinating Centre within 5 working days of receiving the form.
6. National Coordinating Centre to scan and upload a signed copy of the approval form onto the MMEx and also forward to the Local Transplant Centre via email.
7. Once the Local Transplant Centre receives the signed copy of the approval form, Donor and Recipient Agreement to Participate can be obtained.

Agreement to Participate

- ◊ Once Ministerial Approval has been gained, the Local Transplant Centre can complete the Agreement to Participate Forms.
- ◊ Obtain signed Agreement to Participate Forms for the donor and recipient pair to participate in the AKX Programme.
- ◊ Submit the Signed Agreement to Participate Form to the National Coordinating Centre via fax, post, email or MMEx upload.

If the Agreement to Participate will be signed in the NT, approval must be sought from both the NT and the SA Minister for Health.

- ➢ **For all jurisdictions: note that if participants withdraw their approval and subsequently re-enter the programme there will need to be a new approval given.**

Australian Paired Kidney Exchange Programme - Sample draft briefing note for ACT, TAS, NSW, WA, SA and NT

Date:

1 ISSUE

Participation in the Australian Paired Kidney Exchange Programme.

Type of briefing

For information and ministerial approval of an incompatible donor-recipient pair to participate in the Australian Paired Kidney Exchange (AKX) Programme, in accordance with the relevant State Human & Tissue Transplant Act.

Reason for briefing

Approval of the entering into of a contract or arrangement that may result in a paired kidney donation between incompatible donor-recipient pairs, that would, but for the approval, be void under the State Human & Tissue Transplant Act.

2 BACKGROUND

- The increasing demand for donated kidney organs for transplantation and the static deceased organ donor numbers necessitate the alternative of living kidney donation to meet demand.
- Successful kidney transplantation is the best treatment clinically for suitable candidates and it is highly cost effective for end stage kidney failure, with long term results from living donor transplants being far superior to those from cadaveric donors.
- However, 30% of potential donors fail to fulfil their wish to donate to a family member or friend due to a blood group or immunological incompatibility. The AKX Programme is one option for utilising available organs from live donation, in an environment of critical shortage of donated cadaveric organs and ever-increasing demand for transplantation.
- Formal Paired Kidney Donation programs operate in the Netherlands, Korea, United States, and in the United Kingdom.

3 CURRENT STATUS

- The AKX Programme is an extension of existing and established technology for live donor kidney transplantation. Kidney transplantation from a live donor to a recipient accounts for 43% of kidneys donated in Australia.
- Any patient with end stage kidney disease who is eligible for a kidney transplant is able to participate in the AKX Programme. Potential recipients must have a living donor who is willing but unable to donate because of an incompatible blood group or tissue type. The donor must also be willing to take part and to donate his or her kidney to someone else.
- Transplantation of incompatible donor-recipient pairs by AKX is dependent on accurate and reproducible tissue typing results and data entry. It is based on recognising acceptable HLA antigen mismatches and dedicated Tissue Typing laboratories in each State provide this information, with the assistance of the National Coordinating Tissue Typing Officer.

4 BENEFITS OF THE PROGRAMME

1. Saving more lives of Australians on dialysis waiting for a kidney.
2. Giving a larger number of renal patients the opportunity for a better quality of life and the ability to earn an income.
3. Reducing the demand on hospital resources usually required for patients on dialysis.

4. Avoiding costs that would be necessary to support patients who would remain on dialysis (average annual costs ~$53,800
per patient) instead of the cheaper option of kidney transplantation (average annual costs ~$25,000 per patient).
5. The first Paired Kidney Exchange in Australia was performed in Perth in October 2007 (an amendment to the State Human & Tissue Act allowed for this in Western Australia). Based on the completed transplants within the first 2 years of activity, the annual cost avoidance for WA with 11 transplants in patients who would have otherwise remained on dialysis equates to $465,000. This is based on the weighted average dialysis costs (for patients remaining on dialysis), the costs of a transplant in the first year and subsequent years (for patients receiving a transplant) and taking into consideration a 5-year 10% failure rate (transplant patients returning to dialysis). If this is extrapolated nationwide, with a projected estimate of 25 or more extra transplants per annum, cost savings would equate to a minimum of $1,056,825 annually.

Recommendation(s)

The Minister for Health or their delegate

1. Notes the above information; and
2. Approves the participation of the donor-recipient pair in the Australian Paired Kidney Exchange Programme.

Contact for further information

- Director, Australian Paired Kidney Exchange Programme (AKX)
  Department of Nephrology
  Prince of Wales Hospital
  Randwick NSW 2031
  Tel: 02 9382 4411

- AKX Programme Coordinator
  Department of Nephrology
  Prince of Wales Hospital
  Randwick NSW 2031
  Tel: 02 9382 4476

- State Jurisdictional Representative

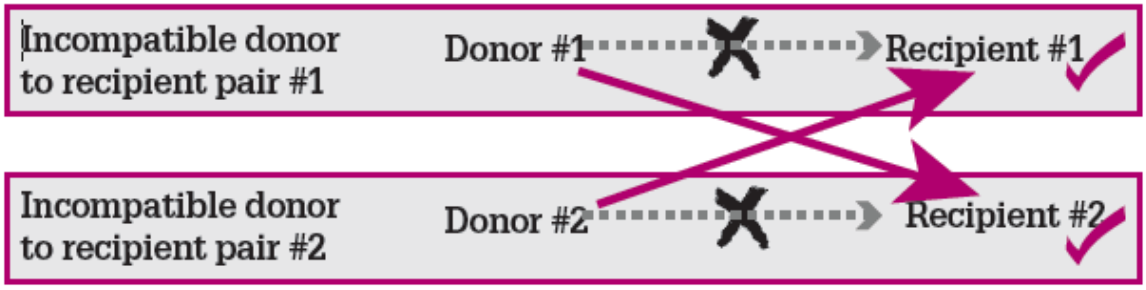
Agreement to participate for donors and recipients

(NSW, WA, ACT, TAS, QLD, VIC, NT and SA)

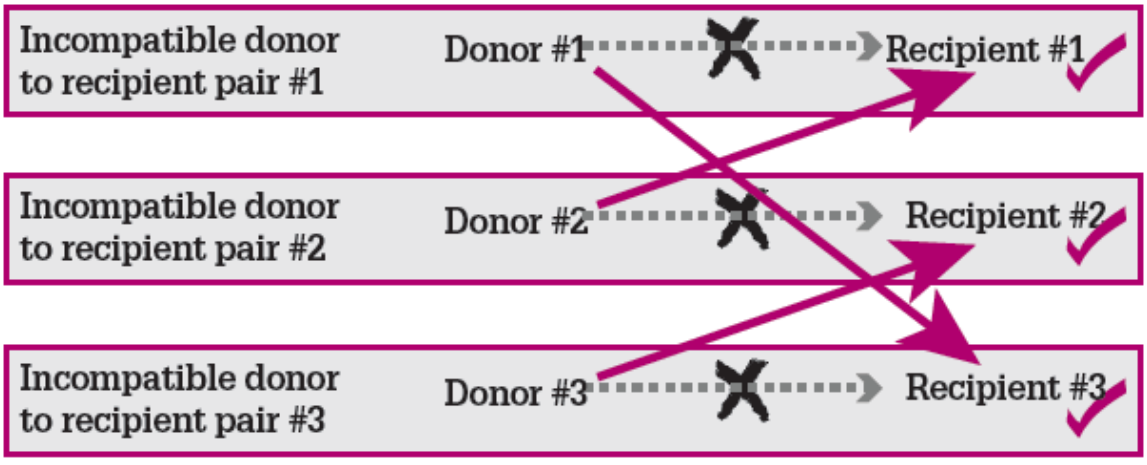
What is the Australian Paired Kidney Exchange Programme (AKX)?

The Australian Paired Kidney Exchange Programme (AKX) is a nationwide live kidney donor exchange programme. The goal of the AKX Programme is to increase live kidney donor transplants by helping incompatible donor-recipient pairs. Participants in the AKX Programme include individuals in need of a kidney transplant and those who wish to donate a kidney to a known potential recipient at an Australian transplant centre, such as a partner, family member or close friend, who cannot do so because of an incompatible blood type or tissue match, or other incompatibility. The AKX Programme seeks to identify donor-recipient pairs in the same situation and to organise an exchange of the donors' kidneys to achieve two compatible transplantations.

In a conventional paired donation (2-way exchange), two donor/recipient pairs overcome each other's incompatibility problem by simply exchanging donors. The pictorial example shows how each willing donor could fulfil their wish to donate a kidney that would be exchanged and transplanted into an unknown recipient. Both the recipients would undergo transplant procedures at their own hospitals.



Paired donations can also be arranged involving three (3-way-exchange) or more pairs, as shown in this diagram.



The AKX Programme has been established to help find another registered pair who might be a match with you and your donor. By exchanging donors, two compatible matches would be created.

A recipient may only enter the programme if they have one (or more) willing but incompatible donor/s. A recipient alone may not enter the programme. Non-directed (altruistic) kidney donors, who wish to give a kidney to any suitably matched recipient on the waiting list, may have their kidney allocated to an individual in this living transplant programme.

This programme is one option if you are incompatible with your proposed donor, but there is no requirement to enter the programme and you may choose not to. Potential donors and recipients receive separate information sessions, so that each person can make up their own mind. The opportunity to decline or withdraw consent is available to the donor and the recipient at any time. No reason or explanation is required.

What are the benefits of participating?

The AKX Programme is voluntary and participants can withdraw at any time. There is no guarantee that you will receive any benefit from participating in the AKX Programme. However, the more donor/recipient pairs that enter the AKX Programme, the more likely it is that you will be part of a pair identified for a possible exchange. If successful, recipients receive a live kidney donation, and donors may receive the psychological benefit of donating a kidney to an individual in need.

The risks and benefits of the donation operation and the transplant operation will be discussed with you in detail by the appropriate transplant centre to help you decide whether to move forward with a donor-recipient exchange. The risks and benefits are no different to living kidney donation from a directed donor.

Agreeing to participate in this programme does not in any way commit you to donate a kidney or to consent to any operation. You may withdraw from the AKX Programme at any time without the need to give a reason.

If I agree to participate, what is the procedure?

The AKX Programme works by entering medical and other details of willing but incompatible donor/recipient pairs into a computer database. At 3-month intervals, the database searches for possible donor-recipient pairs (a 'match run'). Your doctor will notify you at that time if another potentially compatible pair has been identified with whom a kidney exchange may be possible. A tissue match (crossmatch test) is then performed. If the crossmatch test confirms that the proposed transplants are compatible, then each donor and recipient and their respective transplant teams (for example, the surgeon and nephrologist) need to agree to proceed.

Before entering the AKX Programme, donors undergo a full medical evaluation, including psychological assessment by the transplant centre. If all parties consent and the clinical evaluations are acceptable, the donor surgical procedures occur simultaneously, even when performed at hospitals in different states.

Participants may remain in the AKX Programme as long as they remain medically eligible and willing to participate. During this time, the recipients who are on the deceased donor waiting list remain on this list. Pre-emptive recipients (those who have not yet commenced dialysis) may also be eligible to participate in the AKX Programme, if they are deemed suitable for transplantation and have an incompatible donor.

Are there any special considerations specific to the AKX Programme?

If you consent to participate, it is important that you are aware of the following points:

1. The medical suitability of a donor will be tested using nationally agreed medical criteria and the safety of the donor and the quality of the kidneys potentially involved in paired kidney exchange will be assessed. Part of this process includes the completion of the Donor Declaration Form and tests to exclude transmissible disease prior to surgery.

2. Older donors (up to 70 years of age) may be accepted in the AKX Programme if they meet the minimum acceptable level of kidney function to be eligible for this programme.

3. Blood group O donors will be preferentially matched with blood group O recipients. This is to give those recipients the fairest chance of receiving a transplant since blood group O recipients frequently have to wait longer on the transplant waiting list. Highly sensitised non-blood group O recipients, whose chances of finding an acceptable match are low will also receive preferential matching with O donors.

4. Recipients who are on the deceased donor transplant waiting list remain active on the list until a match run occurs. Match runs occur every 3 months, unless no new participants have been enrolled. If no match is found, recipients remain on the deceased donor transplant waiting list. Recipients from matched pairs will be off the list until the transplant can occur. This may be a period of several weeks, and in some instances, the transplant may also be scheduled after the next match run. Matched recipients are not included in any match runs or deceased organ donor allocation during the surgery waiting period. This is to ensure that this chain of transplants remains intact and no recipient is disadvantaged by a transplant not going ahead due to an alternative match being found, either from a deceased donor or another live donor from a match run. If further tests show that the exchange is not possible, the recipients will immediately go back onto the waiting list. Likewise, matched pairs are also immediately returned to the programme database, and will be included in subsequent match runs.

5. It is possible that a donor/recipient pair will be matched to a suitable pair in another state. In this case the kidney will be transported to the recipient. This is because transporting kidneys does not affect the success of the transplant. Donors will not be required to travel and will have their kidney removed at the unit where they have been assessed.

6. The donor operations occur at the same hospital where donors have been evaluated with their originally intended recipient. In some cases, donors and recipients are in different states and are assessed at different transplant centres. In these instances donor and recipient surgery will still be carried out at the transplant centre where the donor and recipient have been evaluated. The donor kidneys are then transported to the matched recipients' transplant centres.

7. It is possible that surgery may be postponed or cancelled at any time in the lead-up to the scheduled day of surgery. This may be due to unforeseen circumstances such as acute illness, or, very rarely, participant's withdrawal from the programme.

   – In the event that surgery is postponed, matched recipients remain suspended from the transplant waiting list and any subsequent match runs until the transplant occurs. The rationale for this is the same as that mentioned in point 4 above that is, to ensure that no recipient is disadvantaged by a chain of transplants being broken should an alternative match be found.

   – In the event that surgery is cancelled, recipients go back onto the transplant waiting list and donor-recipient pairs are included in the next and subsequent match runs.

8. If a transplanted kidney fails, the recipient will be assessed and treated as appropriate. This may involve going back on the transplant wait list, receiving dialysis if required, and considering whether they have other potential donors, as would occur if any other kidney transplant failed.

Are altruistic (good samaritan) donors accepted in the AKX Programme?

Non–directed (altruistic) kidney donors or good samaritan donors are accepted in the AKX Programme as long as they satisfy the donor suitability criteria. Altruistic kidney donors can be referred directly into the AKX Programme or may be first matched against the highly sensitised recipients on the deceased donor transplant waiting list. If no match is found, these donors are allocated into the AKX Programme, as this type of donor often optimises the effect on the number of transplants this brings.

1. When paired donations are initiated by an altruistic donor, they can result in a longer chain of transplants than would have been possible with a normal donor-recipient pair match run.

2. Altruistic donor chains result in an AKX donor who is the last link in the chain, without a reciprocal recipient. This donor is known as an "orphan donor". In this instance, the donor kidney is donated to a recipient on the deceased donor waiting list in the State of origin of the altruistic donor who started the chain.

3. Surgical procedures with altruistic donor chains do not necessarily have to be performed simultaneously.

What if I withdraw my agreement to participate?

Refusal to participate in the AKX Programme will result in no penalty or loss of benefits to which you are otherwise entitled. Choosing not to join the AKX Programme will not affect your chance of receiving a kidney through the national deceased donor transplant wait list.

What happens if one of the kidneys cannot be transplanted?

There is a remote possibility that a transplant may not be able to proceed as planned, even if donors have agreed to simultaneous operations. There are potential scenarios that may result in the following:

Orphaned kidney – this refers to a kidney removed from an AKX donor that cannot be transplanted into the matched recipient.

- A recipient may suddenly become too sick to proceed at the time of transplant and the transplant procedure needs to be abandoned, although the donor has already had a kidney removed in readiness ('orphaned kidney'). As a donor, you will be asked to consider whether, in this rare circumstance, you would be prepared for that kidney to be allocated to a suitable recipient on the transplant waiting list.

Orphaned recipient – this refers to an AKX recipient that has not received a kidney from a matched donor.

- A donor may unexpectedly become unstable during the donor operation and too sick to proceed to having a kidney removed. There is also a possibility that a kidney removed from the exchange donor may not be able to be transplanted into the intended recipient for other reasons. This means that the intended recipient cannot receive a kidney ('orphaned recipient'). In that circumstance, the 'orphaned recipient' will receive priority allocation on the deceased donor waiting list for a suitable kidney.

- In exceptional circumstances, a kidney donated by a live donor elsewhere may suffer irreversible damage before it reaches the recipient's transplant centre.

- If the damage is obvious to the transplanting team, the kidney will not be transplanted. The same priority for allocation of the next available and suitable kidney from a deceased donor would apply as outlined above.

- If the kidney is transplanted and reperfused, but it never worked, priority will not be given to this recipient.

What costs are involved?

There is no cost to you for participating in the AKX Programme. You may need to consider your personal sick leave arrangements if you are employed as you will need to take time off work. This should be discussed with your transplant centre.

No payments can be charged, or paid to you for donating a kidney or participating in the AKX Programme, and there is no compensation available and no claim can be made if a planned exchange does not proceed.

The Australian Government announced a two-year pilot commencing on 1 July 2013 and ending 30 June 2015, to support leave for living organ donors. The pilot is intended to alleviate some of the financial burden of living organ donation by providing a payment to employers, to be passed on in the form of paid leave to employees who are unable to work for a period of time because they have donated an organ. A review of the initiative will occur in 2014-15.
For general enquiries regarding the scheme, please email: livingorgandonation@health.gov.au.

Reimbursement of reasonable medical expenses can be obtained in most States. This should be discussed with your transplant centre.

What are the legal requirements for an organ exchange in Australia?

For paired kidney exchange to be legal in New South Wales, South Australia, Western Australia, the Northern Territory, Tasmania and the Australian Capital Territory, the Minister for Health is required to approve participation in the AKX Programme. Your name and some details will therefore be provided to the Minister prior to registration on the AKX Programme. The Minister for Health, or his or her designated officer, will have to be reasonably satisfied that no monetary payment or reward will be made, given or received for an exchange of kidneys, and that you are entering into this arrangement of your own free will and with full understanding of the associated risks and benefits.

Can Donors and Recipients Meet?

Sharing information and meeting your donor or recipient can cause problems even if there are good medical results. Consequently the AKX Programme protects the anonymity of donor and recipient pairs by maintaining strict privacy and confidentiality for each donor/recipient pair.

The Australian Human Tissue Acts and the Commonwealth Privacy Act 1988 specify that it is an offence to disclose information concerning the deceased, the use of retrieved organs and tissues, and information about recipients. While the Acts do not legally prevent families and others from disclosing or actively seeking information in order to identify donors or recipients, this is strongly discouraged due to the potential emotional implications.

AKX staff are not permitted to facilitate meetings of donors and recipients following transplants.

To ensure confidentiality and anonymity is maintained, donors, recipients and their families should not participate in media interviews prior to the exchange taking place. Engaging with the media prior to an exchange may result in private and confidential information being divulged to the public which could jeopardise the exchange proceeding.

In the event you are contacted by the media to share your story, and you are interested in participating, you should contact the AKX Programme Coordinator immediately to discuss the request.

What information about you will be entered into the AKX Database and how will the data be used?

If you agree to participate, you must consent to have information relevant to an organ exchange entered into the computer database. This information includes, but is not limited to: name, date of birth, relationship between donor and incompatible recipient, blood type, current medications and other health information.

More detailed clinical information for identifying potential donor-recipient pairs will be provided by the transplant centre where you or your originally intended recipient is listed.

Once a match is identified, the images of the donor kidney (CT scan) will be provided to the transplanting surgeon on a CD-ROM to ensure maximum safety of the procedure for both the donor and the recipient. To make sure that the right images are supplied to the right team the transplanting team will receive an identified copy of your CT scan. The sharing of this identifiable data is necessary at this point. In accordance with local state and territory legislation transplant surgeons will maintain confidentiality of your data, and will not disclose your identity to any other members of the transplant team or recipient.

Data entered into the AKX database will be used to identify potential donor-recipient pairings to maximise the number of transplants that can be achieved.

The kidney transplant team including programme staff, physicians and surgeons will review possible donor-recipient pairings. However, under no circumstances is this data provided to participating donor-recipient pairs. Your transplant team will give you as much information as is possible for you to make an informed decision about any potential transplant. The data will be stored indefinitely unless, or until, a participant asks to withdraw or is no longer medically eligible.

Will data be used for purposes other than the AKX?

Data may also be used to provide information to the Australia and New Zealand Dialysis and Transplant Registry (ANZDATA). Most recipients on dialysis will have previously provided consent to be part of this registry. Living kidney donors also need to consent to be included in the registry. The ANZDATA database remains confidential and is only used to provide annual statistics on dialysis and transplantation within Australia and New Zealand. Identities of the registrants are not disclosed. Inclusion on this registry is entirely voluntary. This information will help improve the quality of the AKX. Information collected, in addition to that mentioned above, will consist of medical tests performed prior to transplantation, the exact type of surgery performed, and progress of the donor after transplantation.

How will confidentiality be maintained?

Information collected will be entered into a database by a Programme Coordinator, and staff, physicians, surgeons and the AKX Programme Director and Coordinator will review your information. Otherwise, your information will remain confidential to the extent required by law. Access to the database is through a secure, password protected system and all paper copies of this information are stored in a secure location. Your information will not be shared with other AKX donor-recipient pairs, anyone outside the programme or the participating transplant centres without your permission.

Who do I contact if I have questions?

Your transplant team will discuss all the conditions of participation in the AKX Programme with you. It is very important that you clearly understand these conditions prior to consenting to participate in the AKX Programme.

If you have questions at this stage, please contact your Living Donor Coordinator at your local transplant centre.

For further information contact:

Director, Australian Paired Kidney Exchange 9AKX) Programme
Department of Nephrology
Prince of Wales Hospital
Randwick NSW 2031
Phone: 02 9382 4411

AKX Programme Coordinator
Department of Nephrology
Prince of Wales Hospital
Randwick NSW 2031
Phone: 02 9382 4411
Email: claudia.woodroffe@health.wa.gov.au
Phone: 02 9382 4476
Fax: 02 9382 4409

Web: www.donatelife.gov.au/the-authority/the-australian-paired-kidney-exchange-programme

National Guidelines for AKX Packaging and Transport

1. Introduction

The Australian Paired Kidney Exchange (AKX) Programme is a nationwide live kidney donor programme. The goal of AKX is to increase live kidney donor transplants by identifying matches for incompatible donor-recipient pairs. Consistency across all centres is essential for the success of the programme.

For the purpose of recruiting and assessing donor-recipient pairs, 22 transplant centres have been identified to participate in AKX.

The purpose of this document is to inform **transplant centres performing donor nephrectomies and those performing the transplant in the recipient** of the Organ Packaging and Transport Protocol for the AKX Programme. This Protocol must be followed by participating transplant centres in order to ensure consistent and positive transportation and packaging outcomes.

A pocket guide containing this protocol will also be available to Renal Transplant Coordinators for use on the day of surgery.

The National Coordination Centre (NCC) will assist transplant centres with the coordination of the exchange process and provide logistical support with packaging and transportation of kidneys.

2. Packaging and transport – General principles

2.1. Process

Under the AKX Programme all live donor kidney procedures will occur at the donors' state transplant centre and the kidney transported to the recipients' state transplant centre.

The state transplant centres involved in the exchange of live donor kidneys will be determined by the locations of the donor/recipient pairs identified as suitable exchange pairs by the National Organ Matching System (NOMS).

After formal cross-matching and confirmation of surgical viability by transplant surgeons, the NCC will inform participating centres and confirm a mutually agreeable date for the donor-recipient transplant procedures. The donor procedures will commence at the same time at the two or more state transplant centres. A telephone hook-up between centres and the NCC will occur at the agreed donor anaesthetic start time to ensure arrangements are synchronised and coordinated including transport times and kidney transplant procedures at the respective state transplant centres.

The choice of surgical technique used for the donor nephrectomy will be that which is ordinarily used at the donor hospital. Prior to confirmation of a potential exchange occurring, transplant donor and recipient surgeons will have communicated with each other to discuss any possible surgical issues and confirm which kidney will be removed from the donor, and the viability of the exchange (refer to AKX Surgical Check List).

2.2. Transportation of Kidneys

In the AKX Programme, kidneys will be transported between the donor and recipient transplant hospitals.

Designated AKX transport boxes, trolleys and labels (AKX Transport Pack) will be supplied to each transplant centre. Distribution of AKX Transport Packs to all donor and recipient participating centres will occur prior to the first and subsequent exchange surgeries for transplant centres. At least two weeks prior to each exchange, the NCC and Transplant Centres will ensure an AKX Transport Pack is available for transportation of the kidney. Further supplies to replenish stock will be provided on request over the duration of the AKX Programme. A transport carrier will be used to transport all kidneys between transplant hospitals. The carrier will provide comprehensive door to door service.

Funding for courier services will be the responsibility of the Organ and Tissue Authority.

2.3. Preservation of the Donor Kidney

There will be no single mandatory perfusion solution to be used for the transport of kidneys within the AKX Programme. The final choice of perfusion solution will be negotiated between donor and recipient surgeon at the time of donor CTA review (refer Surgical Checklist).

- The preferred pre-flush solution as per local practice is acceptable
- For intra-state exchanges in NSW and VIC Ross (or similar) solution is preferred. Ross perfusion solution is also acceptable for exchanges across the eastern & southern seaboards (QLD, NSW, VIC and SA)
- For inter-state exchanges that involve WA, UW solution as preservation for packaging purposes is preferred

The donor kidney will be flushed at 100 cm H2O pressure on the back table by the donor surgeon or the surgical assistant with 300ml of perfusion solution (refrigerator temperature of about 4°C if UW solution is used) until venous effluent is clear of blood. The final flush will be performed using a perfusion solution containing either no heparin, 10,000 or 20,000U heparin per litre of perfusate, as determined by the recipient surgeon (refer Surgical Checklist)

Dissection of the donor vessels in the hilum of the kidney on the back table will not be undertaken by the donor surgeon. This will be the responsibility of the recipient transplant surgeon. However, the donor surgeon will ensure completeness of the perfusion of the kidney by external examination of the parenchyma. To enable assessment of complete perfusion of the kidney, the donor surgeon will remove sufficient peri-renal fat tissue, but will not dissect donor vessels.

Post nephrectomy, the donor surgeon should call the recipient surgeon to discuss any anatomical issues that may be of concern. Information on any significant technical or anatomical problem is also to be documented on the Living Kidney Donation report by the donor surgeon.

2.4. Packaging of the Donor Kidney

Packaging of the kidney for transportation will be as for deceased donor kidneys. Specifically, the kidney is placed in three thick sterile plastic bags (e.g. bowel bags). The inner bag will contain the donor kidney and approximately 500ml of perfusion solution. The middle bag will contain 300 to 500ml of sterile cold saline. The outer bag will contain only the two inner bags. No solution is required in the outer bag.

Cold storage for transportation will be provided by a transportable single-use box (filled with non-sterile wet ice) which is supplied to each transplant centre at least two weeks prior to the date of surgery.

The box must be placed in the transport bag provided. The transport bag will be used by all transplant centres. It will allow the kidney box to be more easily manoeuvred, is already screen printed with some relevant labelling and contains a dedicated sleeve for address labels and documentation to travel with the organ.

A collapsible trolley will also be provided to ensure ease of transportation of the filled box.

The Living Kidney Donation Report will be forwarded with the donor kidney. This document has de-identified donor and recipient details, with sections to be completed by donor and recipient centres.

De-identified Donor NAT, Blood Group, CMV/EBV results and Donor blood samples will also accompany the kidney. These documents and blood samples will be placed in the AKX Exchange Details envelope provided, and inserted in the internal sleeve of the dual-compartment document sleeve located on the inside lid of the transport bag.

2.5. AKX Labelling

The transport bag has been screen printed with DonateLife logos and a label indicating the use of wet ice and the necessity for air transport in a pressurised compartment. Specific address labels (marked “Urgent Kidney Delivery”) will be provided by the NCC identifying the bag’s contents and destination, with the contact details of the sending and receiving renal transplant coordinators. The “Urgent Delivery” label is placed in the top sleeve of the dual compartment that is located on the inside lid of the transport bag, so the label is visible from the top of the bag when closed. Transplant centres should also complete the “Exchange Details” envelope label, place the AKX Living

Kidney Donation report, NAT ABO, CMV/EBV results, and donor blood samples in the envelope and insert the envelope into the sleeve that is located on the inside lid of the transport bag.

2.6. Transport Carrier

Transportation of the live donor kidney will be organised by the NCC Programme Coordinator in close collaboration with renal transplant coordinators at the relevant transplant centres. The procedure will be fully coordinated in discussion with the transplant centres involved.

All kidneys will be transported by a transport carrier which will undertake door to door delivery by the fastest possible means and to a designated person (eg. the renal transplant coordinator) at the recipient transplant centre. The renal transplant coordinator, surgeon or delegate will also be responsible for verifying the kidney delivered is the correct one for the recipient, and all documentation is attached and complete. Transport costs will be funded by the Authority.

At least two weeks prior to an AKX procedure, the NCC in conjunction with the local transplant centres, will clearly define the critical issues relating to the logistics of the kidney transport. In particular the timeliness of collection and delivery, security of delivery and any related information or attached documentation will be considered. A transport plan, including an itinerary and contingency plan, will be provided for all kidney transportation (Refer to AKX Organ Transport Itinerary).

3. Packaging resources

An AKX Transport Pack including a single use transport box, lightweight folding trolley and other transport items will be supplied to the transplant centre. The packs are to be designated for AKX use only and kept in a safe and accessible area, e.g. the renal transplant coordinator's office. After each exchange, the NCC will replenish stock of transport packs as required upon advisement from the local transplant centre, to ensure readiness for the next exchange. Please note the transport bag and folding trolley are multiple use items, and as such, should be retrieved from theatres at the completion of surgery.

The AKX transport pack will contain the following items:

- Transport Bag
- Single use box
- Heavy duty clear plastic bag for lining box
- Clear plastic insert tag with loop for labelling of sealed kidney bag
- Transport tape to seal the box.
- AKX Organ Transport Envelope and Label
- Cable tie to seal the transport bag

Standard packaging supplies to be provided by the transplant centre are as follows:

- Preserving fluid – 1L solution x 2 bags
- Heparin
- Bowel bags x 3
- Non-sterile crushed ice
- Sterile cold saline

4. Pre-exchange process

4.1. AKX Programme Coordinator

- Notify transplant teams of the live donor/recipient pairs confirmed for an exchange.
- Coordinate date of transplants acceptable to centres and donor/recipient pairs.
- Identify responsible renal transplant coordinator at each site that will oversee coordination of surgical timelines.
- Identify the transplant recipient surgeon on site (if applicable) who will assist with donor kidney packaging.
- Obtain logistical and operative details pertaining to the day of exchange (refer Day of Exchange Details form)

4.2. Local Transplant Centre

- Obtain consent from donor and recipient for the actual surgery as per hospital policy.
- Ensure AKX transport box and contents are available.
- Check surgical schedules (date & time) are in place.
- Donor NAT has been performed according to AKX protocol.
- De-identified Donor NAT, ABO and CMV/EBV results are available.

4.3. AKX Programme Coordinator Confirms

7-2 days prior to surgery

- Renal transplant coordinators who will be present at kidney retrieval and implant.
- AKX transport packs have been received by each centre and are ready for use.
- Anaesthetic start times and anticipated pick-up time for organs.
- Donor Blood Request Forms for “PKE-Store Cells” have been received by centres
- Name of recipient transplant surgeon who will be present in theatre to assist with packaging (if applicable).

- Flight itinerary for organs (as applicable).
- Consignment Notes for Organ Transport have been received by centres
- Couriers responsible for pickup and delivery.
- Hospital pickup and delivery points and designated contacts at each hospital.
- Contingency plan and emergency contact details.

1 day prior to surgery

- All the above is in place.
- Donor/recipient pairs are fit for surgery (not affected by acute illness, consent not withdrawn).

5. Day of exchange process – Local renal transplant coordinators

5.1. Kidney Retrieval

Designated renal transplant coordinators (or delegates) at each transplant centre will be present in the operating theatre and responsible for the following duties:

i. Donor Blood Sample Collection

- Prior to anaesthetic induction donor blood samples (2 x ACD tubes for PKE –Store Cells) are required from the donor and are to be sent with the kidney to the recipient transplant centre. These blood samples are necessary in the unlikely event of an "orphan kidney"

ii. Communication

Relay the following information via telephone call to the NCC as required:

- Anaesthetic start time – telephone hook up with the NCC and other donor centre(s) to check readiness and synchronised start
- Any delay in scheduled anaesthetic start time
- Time of anaesthetic induction
- Time of knife to skin
- Time of cross clamp of donor kidney
- Time of departure of kidney

The NCC must be immediately notified if:

- **The donor becomes acutely ill at any stage and surgery must be aborted**
- **The kidney may be removed earlier than expected**
- **There are surgical issues that may impact on kidney suitability or readiness for transport**
- **Kidney removed is visibly damaged**
- **Delayed or non-arrival of courier**

iii. Documentation

Ensure the donor documentation is completed appropriately and accompanies the kidney.

Living Kidney Donation Report – Sections 1 & 2

Living Kidney Donation Report

Please complete this form and fax to the AKX National Coordinator on 08 9431 3902 or email claudia.woodroffe@health.wa.gov.au.

SECTION 1: Completed by the Renal Transplant Coordinator or Surgeon present at retrieval and forwarded with donor kidney			
Date of Retrieval		Donor Initials	
		Donor NOMS ID number	
Donor Hospital		Donor Blood Group	
Donor Surgeon		Donor Date of Birth	
Time of Artery cross-clamp		Renal Transplant Coordinator	
Left or Right Kidney		Time Kidney on ice	
No. of arteries		Perfusion fluid / Heparinisation used	☐Ross ☐UW ☐ (specify) ☐10000u ☐20000u ☐None
SECTION 2: Completed by the donor surgery team			
Abnormal findings or damage (short vein/ureter etc)? ☐ Yes ☐ No			
Comments:			
Kidney checked for complete perfusion *(external examination of parenchyma)* ☐ Yes			
Recipient surgeon telephoned post-nephrectomy and advised re any issues ☐ Yes			
Donor Surgeon signature			
Transplant Surgeon signature *(only if donor surgeon is not a credentialed transplant surgeon)*			

iv. Packaging and transport of kidneys

- Correct packaging of kidney
- Address label and "Exchange Details" envelope label completed and the following have been inserted in the envelope:
    - Donor blood samples (2xACD tubes)
    - Completed LKD form
    - De-identified donor NAT, Blood group and CMV/EBV results
- The envelope is then inserted into the document sleeve on the inside lid of the transport bag
- Delivery of the transport box to an awaiting courier

Refer to section 6 for a detailed description of packaging requirements.

5.2. Kidney Delivery

1. Meet courier at designated hospital delivery point - operating theatres reception for example.
2. Ensure incoming Living Kidney Donation Report, Sections 1 & 2 are complete. If not, contact renal transplant coordinator at retrieval centre for details, prior to delivering kidney to theatre.

3. Kidney is checked and verified with implanting surgeon or delegate as correct for the intended recipient.
4. At end of procedure, ensure Section 3 of Living Kidney Donation Report has been completed by surgical team.

SECTION 3: Completed by the Transplanting Surgical team and forwarded to AKX Secretariat within 2 working days of procedure (to above fax number)					
Date of Transplant			Recipient Initials		
Recipient Hospital			Recipient NOMS ID number		
			Recipient Blood Group		
			Recipient Date of Birth		
Transplanting Surgeon			Kidney Side		
Time Kidney off ice			Time of Reperfusion		
No Problems Identified ☐					
Problems Identified *(Please complete if problems were identified)*					
3.1 Inadequate Paperwork	*(Please circle)* **Labelling / donor documentation / recipient documentation**				
3.2 Packaging / Transportation		✓	**3.3 Technical / Anatomical Problems**		✓
3.2.1 Insufficient preservation fluid in bags			3.3.1 Peri-nephric fat not removed adequately		
3.2.3 Damaged container			3.3.2 Incomplete perfusion of kidney		
3.2.3 Other, incl. delays (please specify)			3.3.3 Damaged artery(s)		
			3.3.4 Damaged vein		
			3.3.5 Damaged ureter / insufficient length		
			3.3.6 Non identified abnormal anatomy		
			3.3.7 Non identified pathology		
			3.3.8 Other (please specify)		

5. Fax or scan and email Living Kidney Donation Report to NCC within 2 working days of the procedure.

The NCC must be immediately notified if:

- **The recipient becomes acutely ill at any stage and surgery must be aborted**
- **Wrong kidney is delivered**
- **Kidney not received by the expected time**
- **Transport box damaged and/or packaging inappropriate**
- **Kidney looks visibly damaged when removed from packaging**

6. Perfusion and packaging of kidney

The donor surgeon or assisting surgeon is responsible for perfusion (refer to section 2.3) and packaging of the kidney as described in the following steps.

A transplant surgeon is to be present in theatre to assist with packaging of the donor kidney in centres where urologists not usually involved in deceased donor transplantation (and therefore not familiar with packaging) will perform the donor nephrectomy.

6.1. Kidney Perfusion

1. Donor kidney is flushed at 100cm H20 pressure with at least 300ml of perfusion solution (refrigerator temperature ≈ 40C if UW solution is used) until venous effluent is clear of blood. The final flush will be performed with either no heparin, 10,000 or 20,000U heparin per litre of perfusate, as previously determined by the recipient surgeon.
2. Donor surgeon will ensure completeness of perfusion by external examination of the parenchyma.

Please note any preparation of donor kidney vessels will be the responsibility of the recipient surgeon and is not to be undertaken by the donor surgeon.

6.2. Kidney Packaging

Please note: Steps 1 – 3 are performed as a sterile procedure by the donor surgeon or assistant. 3 bowel bags and perfusion fluid are required.

1. First bowel bag (inner bag) – kidney in 500ml preserving fluid.
2. Inner bag placed in 2nd bowel bag (middle bag) containing 300-500ml cold sterile normal saline solution.

3. Middle bag placed in 3rd bowel bag (outer bag). No solution is required between 2nd and 3rd bag.
4. Completed 'Organ Details' label is inserted into clear plastic tag and tied around the neck of the sealed outer bag.

5. Transport box is lined with a heavy duty plastic bag and 2/3 filled with crushed ice. Sealed kidney is placed upon the ice in the centre of the box, with label facing upwards. Ice is then placed around the kidney, leaving the label uppermost and visible, and ensuring the kidney is stable and no ice covers the label.

6. The neck of the plastic liner bag is secured with any remaining ties from the bowel bags. The organ and ice should be completely enclosed within the plastic liner. Seal the box with transport tape.

7. Completed Living Kidney Donation Form and de-identified NAT, Blood group and CMV/EBV results are placed in AKX envelope, and inserted into the designated section of the transport bag. Donor blood samples (2x ACD tubes) and blood request form placed in specimen bag and included with LKD form in the AKX envelope.

8. Zip the bag closed and bring the zipper pull tags to the front in line with the eyelet and secure with the cable tie.

9. AKX labels with destination details and contact numbers of both sending and receiving renal transplant coordinators inserted into the designated section of the transport bag.

7. Post-exchange

The Living Kidney Donation Report must be returned to the NCC within 2 working days of the procedure. This document will contribute to monitoring of the AKX Programme and will assist in identifying opportunities for improvements to the packaging and transport procedures.

The AKX Programme Coordinator will collect data on the outcome of the transplants and the logistical processes undertaken and report any issues to the Authority and relevant transplant centres.

Protocol for Donor Nucleic Acid Testing (NAT)

Donor Blood Samples must be collected at (or as close to) Day -9 from surgery date.

The window period of 9 days prior to surgery serves a dual purpose:

- narrows the potential window during which a viral infection might not be detected
- allows for clarification of any positive results that may be due to a technical, rather than a true positive result (ie. a false positive result).

All specimen requests must be marked as URGENT to ensure timely receipt of results, as the potential exists for cancellation of surgeries. Ideally, a result should be available within 24-48 hours, and if repeat testing is required, final result must be available within 5 days of scheduled surgery. This allows sufficient time to inform centres of surgery cancellations if required. Please liaise with your local laboratory as necessary to ensure an adequate turn-around time, especially as false positive results are not uncommon.

Once received, the result is forwarded immediately to the AKX Programme Coordinator for de-identification (if not already done so) and then distributed to the recipient transplant centre.
If necessary, a de-identified copy will also be provided to the donor centre as a hard copy of the NAT result will be sent with the donor kidney on the Day of Exchange.

Below is a <u>generic</u> protocol for the collection of NAT samples –please check specific local requirements with your accredited NAT laboratory provider.

Collection and transport of donor samples

1. Specimen collection
   - Test requested must be specified as NAT for HIV, HCV and HBV
   - Donor blood will be collected in two EDTA tubes (purple top), according to manufacturer's instructions
   - Blood collected in EDTA may be stored at 2-30^{o}C for up to 72 hours from time of collection and prior to centrifugation.

   Whole blood should not be frozen.

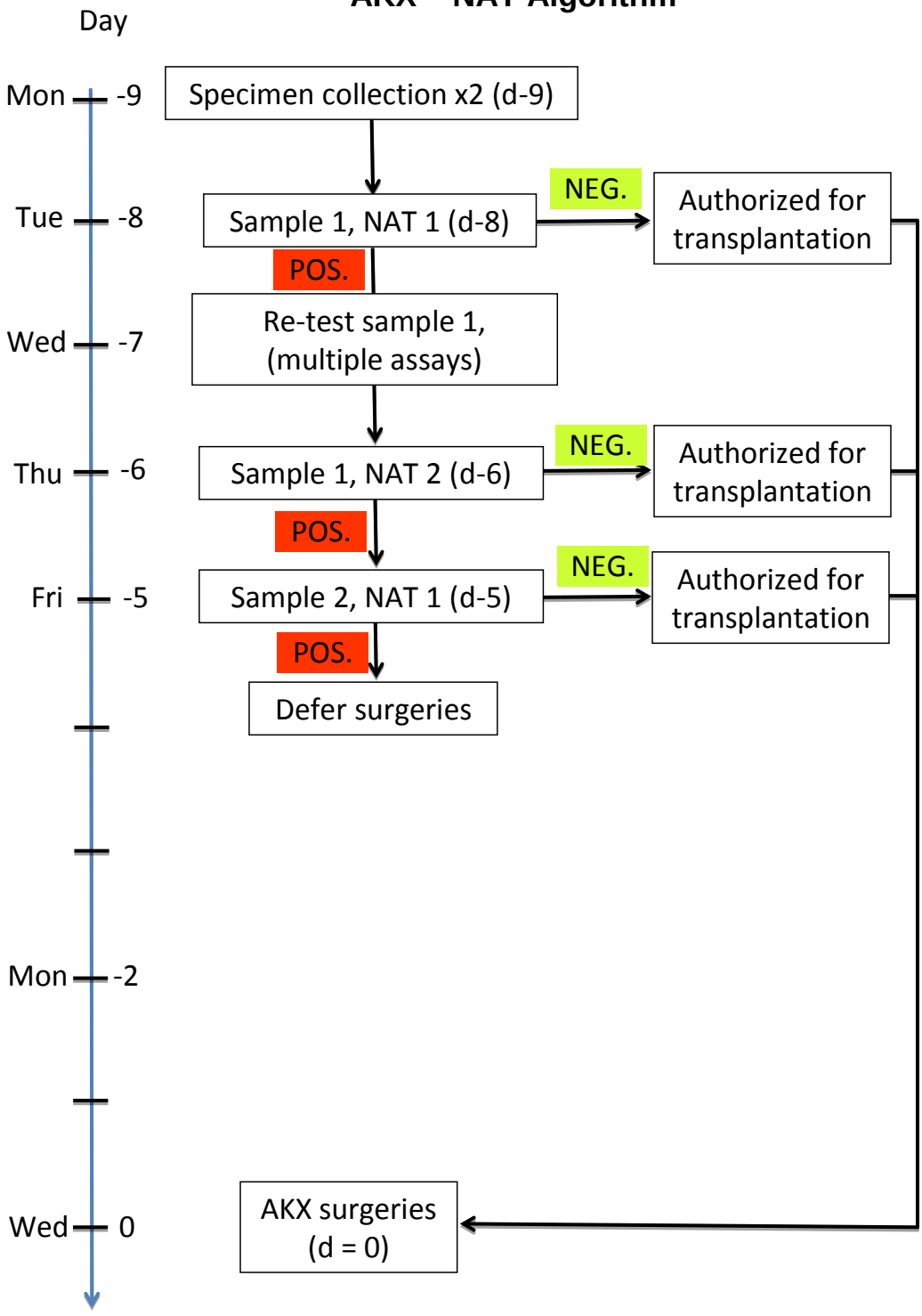
2. Specimen transport

   Specimen must be transported in a suitable container at a temperature between 2-30^{o}C. Each specimen must be placed into a sealed biohazard bag, which contains two compartments - one for the specimen and the other for the request form. Specimens must be sent to an accredited NAT laboratory. A completed NAT Laboratory request form must accompany every specimen delivered to the NAT Laboratory.

3. Non-conforming specimens

   All specimens must be collected, stored and transported as specified above. Specimens not complying with NAT Laboratory specifications, which is in accordance with the NAT test kit manufacturer's instructions, will not be processed.

AKX – NAT Algorithm



AKX recommended donor CTA protocol, reconstruction and reporting standard

AIM

To ascertain number, anatomy (parenchymal and vascular) and function of donor kidneys.
To screen for incidental urinary tract pathology such as tumour, stone, or obstruction.

QUALITY REQUIREMENTS

To be suitable, each CTA needs to be:

- performed with a machine of adequate quality, resolution, and speed
- non-contrast, angiographic, and excretory (IVP) phases must be included, timed appropriately
- an appropriate contrast dose must be given

PROCEDURE

Patient scanned as per protocol below

Reconstructions done as protocol below

Thin images burnt to CD

Radiologist reports using supplied template as the reports basis

The following protocol is a suggestion, not a mandatory requirement.

1. Patient scanned as per suggested protocol

Patient Preparation	• Two (2) hours fasting. Limit fluids to a minimum • Time Out/ Contrast Questionnaire • IV Cannula
Method	• 64 slice scanner • CT Scan utilising a four (4) phase kidney protocol
Summary method	• Non Contrast helical scan of the entire Abdomen/Pelvis • Arterial Phase helical Scan Of the Kidneys (Diaphragm to Crest) • Portal Venous Phase of the Entire Abdo • 10-15 Minute delayed Phase of the kidneys and urinary tract or • Plain X film of the urinary tract performed prone to provide best filling of the ureters
IV Contrast	• 1mL/kg of Ultravist 370 injected at 3.0-4.0 mL/s
Oral Contrast	• None

2. Reconstructions should be in accordance with the suggested protocol below

Reconstruction	**Non Contrast** • 5mm Axial recons **Arterial Phase** • 5mm Axial recons • 2mm Axial recons SMA to inferior portion of the kidneys • 3D semi transparent (AP, 2 Obliques, both Laterals) • MIPs (AP, 2 Obliques, both Laterals) **Portal Phase** • 5mm Axial recons (Diaphragm to Symphysis) **10-15 Minute Delayed Phase** • 5mm Axial recons • 3D semi transparent (AP, 2 Obliques, both Laterals) • MIPs (AP, 2 Obliques, both Laterals)

3. Thin images burnt to CD

CD-ROM	Any CD/DVD should comply with DICOM portable media standards: • DICOM format uncompressed. • There is a DICOM.DIR file in the root of the CD drive. • It can be easily read by Windows XP/Vista/7 & Mac or it provides the software to enable this (Ez-DicomCDviewer).

4. Suggested radiologist reports using supplied template as the reports basis

Aorta

Maximal diameter _____ mm

Calcification: mild / moderate / severe

Native Kidneys

Right		Left
	Renal Length (cm)	
	Cysts (yes/no, size, simple/complex)	
	Scars (yes/no, location)	
	Stones (side, site, size, number)	
	Masses (yes/no, side, size)	
1 / 2 / 3	**Renal Arteries**	1 / 2 / 3
	Abnormalities (FMD, atheroma)	
	Distance aorta – first branch of RA (mm)*	
	Renal Vein length (mm)**	
N/A	**Renal Vein vs. Aorta**	Anterior / posterior
Anterior / posterior	**Renal Artery vs. IVC**	N/A
IVC / iliac vein	**Renal Vein drains into**	IVC / iliac vein
Normal / ectatic / PUJ	**Renal pelvis**	Normal / ectatic / PUJ
Single / double	**Ureter**	Single / double

* *From lateral edge of the aorta to first bifurcation for each artery*

** *From the lateral edge of the IVC (not the middle of the IVC) across to the renal hilum at the medial renal edge (not the innermost hilum)*

Renal Parenchymal Evaluation

- Renal cysts: yes / no if yes: simple / complex size: ____ mm
- Scars: yes / no if yes: location:
- Masses: yes / no if yes: size: ___ x ____ x ____ mm, Location:
- Calculi: Side: Site: Size: Number:

AKX National Contact Details

AKX National Coordination Centre
Department of Nephrology
Level 3 High Street Building
Prince of Wales Hospital
High Street
RANDWICK NSW 2031

Clinical Director
Professor Paolo Ferrari
Telephone: 02 9382 4411
Email: paolo.ferrari@sesiahs.health.nsw.gov.au

Programme Coordinator
Ms Claudia Woodroffe
Telephone: 02 9382 4476
Fax: 08 9431 3902
Mobile: 0420 970 358
Email: claudia.woodroffe@sesiahs.health.nsw.gov.au

Coordinating Tissue Typing Officer
Ms Linda Cantwell
Victorian Transplantation and Immunogenetics Service
Australian Red Cross Blood Service
Telephone: 03 9694 3590
Fax: 03 9328 8232
Email: LCantwell@redcrossblood.org.au

Organ and Tissue Authority
Level 6, 221 London Circuit
CIVIC ACT 2600
Postal Address: PO Box 295
Civic Square ACT 2608

Telephone: 02 6198 9800
Fax: 02 6198 9801
Email: enquiries@donatelife.gov.au

Australian Government
Organ and Tissue Authority

NATIONAL MEDIA PROTOCOL
AUSTRALIAN PAIRED KIDNEY EXCHANGE PROGRAMME

1. Purpose

This document provides guidelines for managing and coordinating media requests regarding the Commonwealth Government's Australian Paired Kidney Exchange (AKX) Programme. It aims to support the Organ and Tissue Authority (OTA), participating hospitals and pairs enrolled in the programme to ensure the integrity and confidentiality requirements for this programme are maintained when reporting in the media.

Media management should be a collaborative and coordinated team effort between the OTA and the relevant treating hospital, and these guidelines should be read alongside and supported by individual hospital and jurisdictional protocols governing media management and patient welfare.

2. Background

The media plays an important role in facilitating coverage and awareness of the AKX Programme and promoting live kidney donation to the Australian public. Ongoing community awareness and education is vital to supporting an increase in Australia's live kidney donation, and more broadly community acceptance of the subject of organ and tissue donation for transplantation.

The OTA occasionally receives interest from the media to report on the AKX Programme. Requests by the media are typically for a 'before and after' diary style story, involving a journalist following a pair in the lead up to an exchange, securing footage of the surgery, and then conducting follow up interviews after surgery.

As the AKX Programme is a confidential and anonymous process, the above requests are usually avoided because engaging with the media prior to an exchange poses risks that private and confidential information may be revealed to the public. This has the potential to jeopardise the exchange proceeding and it is therefore recommended that enrolled pairs do not undertake media activity before an exchange.

The standard approach taken to date by OTA, in liaison with participating hospitals, is that media activity is not undertaken until post-exchange, and generally not until the pair are months into recovery. This is to ensure that surgery has been completed successfully and to protect both the pairs and the integrity of the AKX Programme. The 'diary style' stories are generally not pursued and instead OTA provides pairs who have already participated in the programme to share their experience.

While all efforts are made to ensure enrolled pairs do not participate in any media activity until post-exchange, media outlets can at times secure a story without the knowledge of the OTA or the treating hospital. The AKX Participation Agreement forms signed by donors and recipients have recently been updated to provide information regarding the importance of pairs not undertaking media activity prior to an exchange, and encouraging them to contact their transplant team if they are approached by media. This does not guarantee that enrolled pairs, or the media, will not seek out and engage with each other pre-surgery.

3. Protocol – receiving and managing requests

Providing stories to the media must be balanced by jurisdictional legal requirements including the relevant Human Tissue Acts, privacy considerations and ethical standards that apply in these circumstances.

As this is an Australian Government programme it is appropriate that media management is coordinated through the OTA in conjunction with the relevant hospital media unit and, where necessary, the AKX Programme Director.

If the treating hospital chooses to pursue a story independently of the OTA, jurisdictional protocols will apply however it is requested that the treating hospital inform the OTA, and the AKX Programme Director, of their intention to work with the media on a story. As an Australian Government programme it is likely the OTA will be asked to provide a spokesperson for comment, and prior knowledge of the story is beneficial in these circumstances. It is also important to enable the treating hospital to be made aware of any potential sensitivities regarding the exchange.

For unplanned or reactive situations where the OTA or a participating hospital has not made a request to a pair who are the subject of a media story or a focus of public interest, management of and development of an agreed response plan should be coordinated between the OTA and the respective hospital.

For media requests to interview a pair **post-exchange:**

1. For media requests received by the OTA, the OTA will contact the AKX Programme Director with an overview of the media opportunity in order to identify an appropriate pair. This determination is made by the AKX Programme Director in consultation with the relevant treating physician.
2. The OTA, in liaison with the treating hospital, will contact the pair to discuss the media opportunity and with their permission, coordinate the interview and provide advice and information specific to their participation.
3. Upon agreement by the pair to participate the OTA will notify the treating hospital media unit to provide an overview of the media opportunity and the proposed approach for their information.
4. For media requests received by the treating hospital media unit, the media unit will contact the OTA to provide an overview of the media opportunity and the proposed approach (including information about the pair).
5. The treating hospital media unit will coordinate and lead the request and provide an update to the OTA on the outcome.

For media requests to interview a pair **prior to exchange:**

1. For media requests received by the OTA or a participating hospital to identify and facilitate contact with a pair enrolled in an upcoming exchange for interview purposes, the OTA or participating hospital should advise the journalist that:
    a. Unfortunately we are unable to facilitate this request.
    b. There is the potential for confidential information being revealed – this could jeopardise the surgery proceeding.
    c. Offer to identify a pair who has already participated in the AKX Programme.
2. If the request is received direct by the OTA, they will advise the AKX Programme Director of the media request and response, for information in the event the journalist approaches them.
3. If the request is received by the participating hospital, they will advise the AKX Programme Director and the OTA of the media request and response, for information in the event the journalist approaches either of them.

For media requests to interview a pair **prior to exchange** where the media outlet has secured agreement from an enrolled pair without OTA or participating hospital knowledge**:**

1. Receive and evaluate the media request and identify any sensitivities including the potential for breaches of confidentiality requirements.
2. For requests made:
    a. to the OTA – OTA to arrange a teleconference with the AKX Programme Director and participating hospital;
    b. to the participating hospital – participating hospital to arrange a tele-conference with the OTA and AKX Programme Director; or
    c. to the AKX Programme via the National Coordination Centre (NCC) - NCC to arrange a tele-conference with the OTA and participating hospital to ensure all stakeholders are advised of the issue and to develop an agreed response plan.
3. All stakeholders to agree on a response plan, including who will coordinate and lead the request. The coordinating stakeholder will periodically report to the other stakeholders.
4. The coordinating stakeholder will contact the pair and discuss the issue with them, including the option to refrain from engaging further until post-surgery.
5. If the pair elects to proceed, the coordinating stakeholder will contact the journalist to brief them on the privacy issues and seek agreement to hold the story until an agreed date following surgery.
6. The coordinating stakeholder will manage and coordinate the interview requests.

4. Providing information and support to a pair

When communicating with an enrolled pair willing to participate in media opportunities, it is helpful to inform them of the following:

1. Pairs can change their mind about participating in media opportunities at any time prior to the story being aired/published.
2. Unless an interview is live to air, there is always the possibility that the story may not run.
3. Everything that is said to a journalist is “on-the-record” and could appear in the story.
4. Due to the nature of the AKX Programme, it is strongly advised that donors, recipients and their families do not engage with the media until post-surgery.
5. Engagement with the media may result in a pair and their families becoming better known in their community. This is especially the case for families involved in national media or media in a small community, as was the case with one of the families involved in the historic 6-way exchange.
6. In accordance with the AKX Agreement to Participate, pairs should not reveal any information to a journalist or any other party that could allow other enrolled pairs to identify them in the chain (e.g. date of exchange, number of pairs enrolled in the exchange, location of the exchange etc).

5. Altruistic donors

Anonymous non-directed donation provides a new and fascinating angle for the media.

Requests to facilitate contact between altruistic donors and the media should be avoided. While the promotion of altruistic live donation is positive in demonstrating the potential for domino transplants, it could be damaging to the integrity of the Programme.